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NUCLEAR REGULATORY COMMISSION

Title: Development of Proposed Rule to Amend
Training and Experience Criteria in 10
CFR Part 35 for Recognition of Specialty
Board Certifications

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING / ROUNDTABLE DISCUSSION

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DEVELOPMENT OF PROPOSED RULE TO AMEND

TRAINING AND EXPERIENCE CRITERIA IN 10 CFR PART 35

FOR

RECOGNITION OF SPECIALTY BOARD CERTIFICATIONS

+ + + +

TUESDAY,

MAY 20, 2003

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The Meeting commenced at 8:30 a.m., in
Room 01F16, One White Flint North, 11545 Rockville
Pike, Rockville, Maryland, Roger W. Broseus,
Rulemaking Project Manager, presiding.

PRESENT:

ROGER W. BROSEUS	NRC/NMSS/IMNS
HOWARD DICKSON	American Board of Health Physics
RICHARD FEIJKA	Special Board on Nuclear Pharmacy, Board of Pharmaceutical Specialties
WILLIAM HENDREE	American Board of Radiology

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1 PRESENT (Continued):

2 PATRICIA K. HOLAHAN NRC/NMSS/Deputy Director,
3 IMNS
4 ALAN MAUER American Board of Nuclear
5 Medicine
6 ARMANDO RAMIREZ American Osteopathic Board
7 of Nuclear Medicine
8 GARY SAYED American Board of Science
9 in Nuclear Medicine
10 WILLIAM VAN DECKER Certification Board of
11 Nuclear Cardiology
12 KENNETH VANEK American Board of Medical
13 Physics
14 SANDRA L. WASTLER NRC, Facilitator

15
16 ALSO PRESENT:

17 LYNNE A. FAIROBENT American College of
18 Radiology
19 WILLIAM R. UFFELMAN Society of Nuclear Medicine
20 JAMES M. HEVEZI Cancer Therapy and Research
21 Center

22

23

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P-R-O-C-E-E-D-I-N-G-S

(8:36 a.m.)

MR. BROSEUS: There are a couple of people, Kathy Pryor and Dr. Van Decker, who haven't arrived yet, but we need to proceed so we can stay as close as we can to the schedule this morning.

Patricia Holahan, the Deputy Director of our Division of Industrial Medical Nuclear Safety, is going to welcome us this morning.

MS. HOLAHAN: Well, welcome. I trust that I've walked around and met everybody personally. I don't think I met you, but --

MR. HENDEE: I'm Bill Hendee from the American Board of Radiology.

MS. HOLAHAN: Yeah. But we're really glad you could be here, and we think it's going to be good to get your insights directly on the proposed rule as we develop it.

The purpose of the meeting is to obviously get early involvement of the stakeholders, i.e., the boards, to provide input on the proposed rulemaking to change the training and experience requirements for recognition and certifications of specialty boards under 10 CFR, Part 35.

And as background, the ACMUI originally

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1 identified the problem in the Commission briefing
2 last February of 2002, and Part 35 was published in
3 April of 2002, retaining Subpart J to allow the
4 boards sufficient time or us to develop a rule to
5 allow the boards for recognition to develop new
6 options.

7 The ACMUI spent considerable time, and I
8 believe they met with all of you as part of their
9 subcommittee on developing recommendations to
10 develop new criteria during the summer and the fall
11 of 2002, and the staff is now moving forward on the
12 proposed rule based on Commission direction in the
13 SRM, and the SRM was issued February 12th, 2003, and
14 they approved Option 3, which was basically the
15 ACMUI recommendations.

16 The exception was that the rule would
17 have to -- the rule would allow boards to be
18 recognized on the Web site, and also there was an
19 issue with the preceptor statement. They felt that
20 they wanted the preceptor statement as it was
21 written in the original Part 35.

22 So the focus of the meeting, again, is
23 on the T&E criteria and recognition of the boards,
24 and we encourage participation from all of you so
25 the staff may benefit from the knowledge of the

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1 boards in developing a sound and effective rule.

2 Similarly, we had public meetings last
3 year on the guidance, and they were well received,
4 and Alan was there, and I think Dr. Van Decker was
5 there, but it resulted in significant changes in the
6 licensing guidance.

7 So anyway, I thank you all for your
8 participation and your effort. So we're looking
9 forward to having informed opinions, and I'll turn
10 it over to Roger now.

11 MR. BROSEUS: Thank you, Trish.

12 I plan to go around the table and let
13 everybody introduce themselves, but I'm going to
14 hold off for a couple of minutes to see if a couple
15 of stragglers come in.

16 Let me introduce myself. I'm Roger
17 Broseus. I work in the Rulemaking and Guidance
18 Branch. I am the project manager for this
19 rulemaking.

20 I've been at the NRC for it will be
21 three years on Memorial Day, ha-ha, and before that
22 I had a long career working in the biomedical field
23 as a health physicist, 28 years at the National
24 Institutes of Health, and I supported our Radiation
25 Safety Committee, amongst many other activities in

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1 Radiation Safety Branch there.

2 So I'm quite familiar with many of the
3 issues that come up, but I want to also thank you
4 all for being here because some of you came from
5 quite some distance, and I appreciate -- are you not
6 picking me up properly? Okay.

7 I want to thank you all for taking the
8 time to come and cover a couple of administrative
9 items, too. We have public meeting feedback forms
10 over on the table here, along with some other
11 handouts. Members of the public who are here today
12 are welcome to fill these out and send them back in
13 if you wish.

14 We would like to have members of the
15 public sign in. We have a meeting attendance sheet
16 over on the side, and we'll keep one up here
17 someplace, and the handouts, as I said.

18 I think we'll just go ahead and go
19 around the table now. I've introduced myself.

20 You know Trish.

21 Sandy Wastler. Go ahead, Sandy.
22 Introduce yourself and we'll just move around.

23 MS. WASTLER: All right. I'm Sandra
24 Wastler. I'm Chief of the Rulemaking and Guidance
25 Branch, Section A, and unlike Trish and Roger, I've

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1 been in this position six months; been with the
2 agency for 28 years; got a broad spectrum of
3 background from reactors, uranium recovery, but this
4 is a new era for me as far as being involved in the
5 health field.

6 So I want to again extend a welcome to
7 everyone, and thank you for coming.

8 MR. RAMIREZ: I'm Armando Ramirez from
9 the American Osteopathic Board of Nuclear Medicine.

10 MR. BROSEUS: We need to make sure
11 everybody has their button down so that the red
12 shows so that we pick you up for the transcriptions.

13 MR. RAMIREZ: Thank you.

14 Armando Ramirez for the American
15 Osteopathic Board of Nuclear Medicine.

16 MR. BROSEUS: Could you also -- excuse
17 me for interrupting you -- could you also tell us
18 where you're from and a little bit about yourself so
19 that we'll have a little more context?

20 MR. RAMIREZ: Our specialty board is
21 headquartered in Chicago, and we're a small board,
22 but nevertheless our members are interested in
23 maintaining its recognition by the NRC.

24 Thank you.

25 MR. SAYED: I'm Gary Sayed from the

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1 American Board of Science in Nuclear Medicine. I'm
2 the Dean of the College of Health Sciences and
3 professor of radiology at Drew UCLA Medical School
4 in Los Angeles.

5 MR. MAUER: I'm Alan Mauer here
6 representing the American Board of Nuclear Medicine.
7 I was here a year ago as President of the Society of
8 Nuclear Medicine. So I have been involved with the
9 NRC in reviewing the new Part 35 now for almost two
10 years, both from the regulations and the T&E
11 portion, but I'm here primarily representing the
12 board as a member of the board today.

13 I'm Director of Nuclear Medicine at
14 Temple University Hospital in Philadelphia.

15 MR. HENDEE: I'm Bill Hendee. I'm here
16 representing the American Board of Radiology for
17 which I serve as president for a two-year term at
18 the current time. I'm also Senior Associate Dean
19 and Vice President and Dean of the Graduate School
20 of Biomedical Sciences at the Medical College of
21 Wisconsin in Milwaukee, and all of the radiation
22 safety responsibilities fall under my jurisdiction
23 there, and they have.

24 I'm a member of the American Board of
25 Health Physics and all those other things that you

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1 all know so well.

2 MR. FEIJKA: I'm Rich Feijka. I
3 represent the Board of Pharmaceutical Specialties,
4 and currently serve as the chair of the Nuclear
5 Pharmacy Specialty Council within the BPS.

6 I'm a practicing nuclear pharmacist. I
7 work down the street at NIH and have been there for
8 22 years. I'm familiar with Roger because we work
9 together, and NIH, and I'm here to provide direction
10 and input from the nuclear pharmacy group.

11 MR. VANEK: My name is Ken Vanek. I'm
12 representing the American Board of Medical Physics
13 and also as a previous chair of the American College
14 of Medical Physics. I'm here for them, too.

15 I'm currently the Associate Chairman of
16 the Department of Radiation Oncology at the Medical
17 University of South Carolina.

18 MR. BROSEUS: I'd also like to recognize
19 the members of the working group who are doing this.

20 Sally Merchant is in the back. She's
21 with the Office of Enforcement.

22 Susan Shedakel (phonetic) -- raise your
23 hand so everybody can see you, Susan. You're short
24 -- is from OGC.

25 David Walter is here from Alabama. He

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1 is also a member of the working group representing
2 agreement state interests.

3 There are a couple of people who aren't
4 here at the meeting right now. John Zabkos
5 (phonetic) from our Office of State and Tribal
6 Programs. Betty Golden and Beth St. Mary represent
7 some of our administrative and Information Office
8 people.

9 A couple of administrative things.
10 Because of the security here, sometimes you hit a
11 couple of walls coming in, but I have been told by
12 our security people that we will be able to
13 circulate here on the ground floor. So there's a
14 little snack bar next door called the NUREG Cafe,
15 appropriately named.

16 (Laughter.)

17 MR. BROSEUS: And men's and ladies'
18 rooms are right out here also. There's a cafeteria
19 on the other end of the building which I'm told you
20 can go to when we break at the end of the meeting
21 today.

22 Sandy, you have a couple of comments
23 that you want to make a our facilitator.

24 MS. WASTLER: Right. Roger has asked
25 that I help facilitate the meeting today. So I just

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1 wanted to run through a couple of ground rules just
2 to make this as effective and efficient as we can
3 and make the most of the time that we have this
4 morning.

5 Obviously the first thing that we want
6 to do is start on time and stop on time. So we want
7 to try to keep to the agenda. Obviously keep to the
8 purpose of the meeting, as has been discussed by
9 both Roger and Dr. Holahan.

10 And with regard to the open discussions
11 that will start at 9:45 and at 10:50 today, we want
12 to try to provide everybody an opportunity to have a
13 -- you know, provide their input because we're very
14 interested in what you have to say, but we also have
15 to balance that against the time that we have
16 available.

17 There will be additional opportunities,
18 as you all know, to comment during the proposed rule
19 stage, and at the end of the meeting we do have an
20 opportunity for audience or public comments that
21 will happen around 11:30.

22 And as has been noted, we have a
23 transcriber here. So if you could, you know, try to
24 make sure that you have your speakers on, and if you
25 can, say your name before you launch into your

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1 comments. It makes it easier for the transcriber in
2 the long run.

3 And I'd just say that if you, you know,
4 as we open the discussions, if you have a question
5 or want to make a comment, you can just sit
6 something, you know, your name tent, on end, and
7 we'll try to -- I will try to call folks as you've
8 done that. I make my best effort to do that.

9 But we want to give everybody an
10 opportunity to provide comment to us, but we also
11 understand that there's other meetings today. ACMUI
12 is going on starting at one o'clock. So it's really
13 imperative, I think, that we try to keep to the
14 schedule and make the best use of our time.

15 So thank you.

16 MR. BROSEUS: I'd like to proceed with
17 the presentation to give you all some background
18 before we launch into discussion, but before I do
19 that, I want to reemphasize what Trish and Sandy
20 have said, and that is that we're here to get your
21 input early on in this proposed rulemaking. My ears
22 are wide open, and I'm dedicated to having this come
23 out to be the best possible rule, making sure
24 stakeholder interests are balanced, and so on.

25 I've learned, by the way, at the NRC

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1 that as an internal stakeholder the things don't
2 always come out the way I want them to be, but we're
3 going to try to make the best rule possible.

4 Let's go on to the next slide, please.

5 I'm going to go through and redefine the
6 problem here a little bit. Trish touched on this,
7 but I think that it's useful for people to know what
8 the history is on this.

9 Part 35 is scheduled for publication in
10 the spring of 2002 as a major revision of the
11 medical licensing rule. This is the rule that the
12 NRC exercises its licensing authority over the use
13 of byproduct materials in medicine.

14 In February of 2002, ACMUI identified
15 before the Commission in a briefing a problem, and
16 that is that the specialty boards, who certify
17 authorized users, radiation safety officers,
18 authorize nuclear physicists, authorize medical
19 physicists -- did I say it twice? -- nuclear
20 pharmacists and medical physicists, okay, many or
21 most of them wouldn't meet what was in the rule.

22 And so this concern and some other
23 concerns, but primarily this concern, led to the
24 reinsertion into Part 35 of Subpart J and which
25 boards continued to be recognized in the rule.

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1 Next slide, please.

2 MS. HOLAHAN: Copies are being made for
3 all of the people around the table or around the
4 room of the slides.

5 MR. BROSEUS: Sorry not to have those
6 this morning. I was kind of putting things together
7 at the last minute here.

8 Okay. So subpart J was retained in the
9 rule effective through October 24, 2004.

10 The Commission also directed staff to
11 work with ACMUI to come up with a solution to the
12 problem. ACMUI put together a subcommittee and
13 developed proposed rule text and other material to
14 solve the problem, and this material was presented
15 to the Commission in a SECY paper last year in the
16 fall with three options.

17 And the three options, the first one I
18 would call a non-option. That was to leave things
19 in the status quo, and of course, that continued the
20 obvious problems we see.

21 The second one was options developed by
22 ACMUI which included some proposed rule text to set
23 forth criteria for recognition of boards and some
24 other matters.

25 The third option that went to the

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1 Commission was essentially the second option, with
2 the addition by staff of recommending that
3 recognized boards be listed on NRC's Web site rather
4 than explicitly in a rule.

5 Now, this had several advantages. One
6 of them was you don't have to change the rule every
7 time you list the board.

8 The Commission accepted the third option
9 and communicated in a staff requirements memo, SRM,
10 SRM-02-0194, which we have on the slide, and that's
11 where we're at today. We're working with the SRM,
12 the direction to staff, to develop a proposed rule.

13 The SRM -- next slide, please -- the SRM
14 directed the staff to modify T&E requirements,
15 training and experience requirements, in a proposed
16 rule based on ACMUI's recommendations.

17 As I mentioned a moment ago, the SRM
18 also said we should list boards on a Web site, not
19 in the rule. Also, direction to the staff: keep
20 the preceptor statement as written in the current
21 rule, but clarify it to indicate that the
22 attestation in the preceptor statement was not an
23 attestation of clinical competency, but required
24 that this attestation be sufficient to demonstrate
25 that a candidate for RSO, AU, whatever had

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1 sufficient knowledge to fulfill the duties for the
2 position for which the certification was sought.

3 Now, some of these clarifying statements
4 that I just mentioned and other matters, the staff
5 approach to this is not to put them into rule text,
6 but to have them in supplementary information, which
7 will be published with a proposed and final rule.

8 When a rule is published, there's sort
9 of what I call a preamble, which gives some
10 background on the rule, and so on, but there's also
11 the discussion of the rationale for the rule, and
12 many times discussion of how a rule will be
13 implemented. And this is where we expect to see the
14 clarifications about the preceptor statement, in the
15 supplementary information that accompanies the rule.

16 Next slide, please.

17 Some of the key points in the SRM were
18 to require a clear regulatory determination that all
19 boards meet the criteria that is the criteria set
20 forth in the rule; that we should provide
21 implementing procedures for addition to or removal
22 of boards from our list; and if a board is to be de-
23 listed, taken off the list, the staff is to examine
24 certain things to figure out, you know, why somebody
25 should or shouldn't be on the list. Okay?

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1 But one of the directions to the
2 Commission is not to inspect the boards, but to do
3 such things as monitor trends in medical events and
4 see if there's an association between a board
5 certification process or whatever and maybe a root
6 cause for a medical event.

7 We're going to talk a little bit more
8 about the implementation later, but this is one of
9 the areas where we're especially interested in
10 testing your input on the implementation procedures
11 for listing and de-listing boards.

12 Next slide, please.

13 We're now drafting a proposed rule, and
14 the approach of the working group is to use the
15 recommendations of ACMUI in Attachment 2 to the SECY
16 paper. This is the options paper that went forward
17 to the Commission, and there is a copy of this
18 available. Most of you probably have this already.
19 It looks like this.

20 I don't think it's particularly useful
21 to dig it out right now and go through it and read
22 it, but in this Attachment 2 has some rationale of
23 ACMUI for where the proposed rule should go, along
24 with some draft rule text.

25 The Commission and -- I'm sorry -- ACMUI

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1 indicated that they felt that this draft rule test
2 that used should serve as a starting point, but the
3 working group was looking very closely at the rule
4 text and incorporating as much as possible, making
5 changes as appropriate.

6 In the staff's evaluation, we're finding
7 a need for some wording changes. We've also
8 identified a potential need for a change in the
9 recommendation of ACMUI.

10 In some of the recommendations in what
11 I'll call the alternate pathway, I'm going to use
12 some terminology today to kind of make things -- how
13 shall I say? -- to categorize the two types of
14 training and experience requirements.

15 We have board certifications, and then
16 what's in the existing rule now that's not the
17 board's certification pathway, which I will for
18 convenience sake term the alternate pathway.

19 ACMUI made some recommendations in the
20 rule text for changes in the text in the alternate
21 pathway, and the staff is looking at that pathway,
22 too, the recommendations of ACMUI and the language
23 that's there, and we have some suggestions for
24 changes to ACMUI's recommendations in that area
25 also.

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1 One of the things ACMUI recommended in
2 their discussion at the beginning of Attachment 2
3 and was reflected in their rule text was inclusion
4 of what I would call some experiential requirements
5 for various classes of authorizations in radiation
6 safety officers and so on.

7 The idea is that when a person is
8 coming on board as an RSO or medical physicist or
9 whatever, they should have some training and
10 experience in the modalities that a particular
11 licensee would be using, and an example of where
12 this comes in is in 35.390, in their
13 recommendations.

14 And later on when you're looking at this
15 and 390 in particular, this is their last paragraph,
16 little D in parentheses, and when we get into
17 writing the proposed rule, which we're working on
18 now, our numbering system will be somewhat different
19 from what ACMUI had, but I'd like to make sure
20 you're aware that when we are plowing through the
21 proposed rule, we're trying to be sure to reflect
22 the intent of ACMUI in what we're writing.

23 Next slide, please.

24 ACMUI in their recommendations, and I'll
25 call it in the alternate pathway, in Sections 490

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1 and 690, added what I'll call a residency board as
2 an approving entity. It's the Royal College of
3 Physicians and Surgeons of Canada. This is added
4 to the list of approving entities for recognition of
5 residency training programs.

6 We are looking in the working group to
7 establish a basis for adding that board. We need to
8 have a basis, we feel, which we would probably put
9 in our supplementary information for that.

10 So if there are any of the board members
11 that are here that are aware of an appropriate basis
12 for listing or not listing, that might be a topic of
13 discussion today.

14 MR. HENDEE: Well, can I just interrupt
15 for one moment?

16 MR. BROSEUS: Yeah.

17 MR. HENDEE: Just a point of
18 clarification.

19 MR. BROSEUS: Yeah.

20 MR. HENDEE: An organization or entity
21 that approves the residency program is not
22 necessarily the same as a board that certifies
23 individuals in the practice of a specialty. Are you
24 making a distinction here?

25 You can come back to this if you want.

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1 MR. BROSEUS: Yeah, let's hold the
2 question until we get into the discussion.

3 MR. HENDEE: Okay.

4 MR. BROSEUS: Okay. Thanks.

5 Next slide, please.

6 There are a couple of additions that the
7 staff was thinking about for the proposed rule,
8 adding to what ACMUI had proposed. I shouldn't say
9 an addition on the first one. The first one we're
10 talking about the preceptor statement.

11 The SRM required a preceptor statement
12 for both pathways. They also said, "Don't rewrite
13 the preceptor statement." It should be retained as
14 is in the rule.

15 The approach we are taking as staff
16 members in drafting the proposed rule is to take the
17 existing preceptor statement for what I will call
18 the alternate pathway and using that for the pathway
19 for board certification. We can't use it literally
20 because there's some back references or cross-
21 references and inappropriate references in the
22 existing preceptor statement for the alternate
23 pathway that don't quite fit, but we're keeping
24 largely the language and the intent.

25 The other point in terms of I would call

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1 this in addition to the ACMUI text is adding call it
2 an "or" to the board certification pathway. Loosely
3 termed, I see ACMUI's recommendations as
4 substituting an academic plus experience as the
5 basis for board certification.

6 I'm generalizing to simplify for a
7 moment.

8 The current rule says if a board meets
9 the training and experience requirements in Part 35,
10 and there's a whole list of those, 700 hours of
11 training and so on; it's essentially what we're
12 calling today for the sake of simplicity the
13 alternate pathway.

14 If a board meets those, that's the basis
15 for approving certification being recognized.
16 ACMUI's recommendation did not include that pathway.

17 One board is recognized now based on
18 that pathway. It's the cardiology board.

19 Secondly, staff feels that if that
20 pathway is appropriate now, it should be retained as
21 a mechanism by which a board can be recognized.
22 That isn't to exclude what I'll call the academic
23 pathway. Okay? It's an "or" built into the board's
24 certification.

25 Okay. So that's staff thinking, and I

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1 see your hand raising already, and maybe we can save
2 for discussion unless you have something you feel --

3 MR. MAUER: Well, one of my purposes --

4 MR. BROSEUS: Alan Mauer.

5 MR. MAUER: Yeah, this is Alan Mauer.

6 I'm sorry.

7 In some of the documents it has been
8 said that only one board has been recognized as
9 having met the requirements. One of my purposes of
10 attending today is to try and get some clarification
11 because there was a lot of confusion at the American
12 Board of Nuclear Medicine Office.

13 We have a letter to Dr. Van Heardon, who
14 was Chairman of the board in July 2001, from John
15 Hickey when the American board had written and was
16 trying to clarify whether the ABNM would get the
17 dean status.

18 This letter from Mr. Hickey does say
19 that the American Board of Nuclear Medicine does
20 meet the requirements, and it says, "After Part 35
21 is issued in final form, we plan to list on our Web
22 site the boards which have been recognized. We will
23 include ABNM on that list."

24 There seems to have been somehow lists
25 dropped off the radar screen, and now that you're

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1 mentioning it, I was going to bring -- I'm not sure
2 when it's appropriate, but as a part of today's
3 meeting, I would like to get clarification to take
4 back to the board.

5 MR. BROSEUS: I don't think we're going
6 to be able to clarify it in the meeting today.
7 That's a surprise to me. I wasn't aware of it, but
8 I'm sure that we can take this back as staff and
9 examine this.

10 MR. MAUER: Because there's a lot of
11 confusion at our board right now. We have a letter
12 from Mr. Hickey saying that we do meet the
13 requirements, but everything that I've been reading
14 and I just hear you saying is that there's only one.

15 So I'd like --

16 MR. BROSEUS: I'll take that back after
17 our meeting.

18 MR. MAUER: -- to get that clarified.

19 MR. BROSEUS: Trish is alert to it
20 already.

21 MR. MAUER: yeah.

22 MR. BROSEUS: And we'll have to look at
23 it, but it's not something we can resolve today.
24 That's for sure.

25 MR. MAUER: Okay, and I'll show you a

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1 copy of that.

2 MR. BROSEUS: Thank you.

3 If we could move on, so a major point
4 here in this slide is that the staff feels that we
5 need to retain, and we put in I'll call it an "or,"
6 the possibility that a board can be recognized or
7 certification recognized if they meet the existing
8 T&E requirements in the alternate pathway.

9 Next slide, please.

10 I'm getting into detail now. As we were
11 going through ACMUI's recommended rule text, we
12 found some additions and subtractions, and I'll call
13 them at the wording level. One of them is in the
14 training and experience requirements for radiation
15 safety officers and 35.350.

16 Staff has added in in the board's
17 certification pathway radiation dosimetry that was
18 missing from -- I would say it wasn't included. It
19 wasn't one of the criteria that ACMUI included in
20 their wording.

21 Likewise they had dropped radiation
22 dosimetry in 35.50(b)(1)(i)(E). I just love this,
23 you know. I'm still partly from the other side, and
24 we have one, two, three, four levels down in the
25 paragraph numbering system. I used to admire people

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1 from the Nuclear Regulatory Commission who could
2 cite these things from memory. It just awed me in a
3 certain way that only Dilbert could appreciate.

4 But the point here is in the alternate
5 pathway the wording of ACMUI dropped radiation
6 dosimetry as one of the training and experience
7 elements, and staff feels that that's an essential
8 area of knowledge for a health physicist, and so we
9 plugged it in also into the draft text that we're
10 working for the board certification pathway.

11 Also, in the alternate pathway, ACMUI
12 did not include the phrase I have here on the slide,
13 "permanent issue by a Commission master materials
14 license." This is if a radiation safety officer is
15 listed on this sort of license a pathway for
16 recognition of a RSO if they go on to another
17 facility, and I don't think it was ACMUI's intent to
18 drop this pathway.

19 We'll be talking with ACMUI, by the way,
20 about these things, too. So the staff is keeping
21 that phrase that was, I think, inadvertently dropped
22 by ACMUI.

23 Next slide, please.

24 Going to the next slide, we are looking
25 at the terminology in 35.51, and this is for

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1 certification of medical physicists. The text of
2 ACMUI had radiation oncology physics as an area of
3 training. Some staff members feel that medical
4 physics is a more general term and, therefore, may
5 be more appropriate for use in rule language.

6 Also I've noted that the terminology
7 "oncology physics" seems to be tied somewhat to the
8 language that certain boards use, but others don't.
9 And so our feeling is that "medical physics" may be
10 a more appropriate way of characterizing the
11 training that's required for one to practice in this
12 particular area and become an authorized medical
13 physicist.

14 In 35.390, again, we're way down to the
15 detail level now. In one of the sub-sub-
16 subparagraphs, ACMUI is talking about the types of
17 administrations of byproduct materials, IV or
18 orally, and they use the terminology "therapeutic
19 quantities."

20 Thirty-five, three, ninety is talking
21 about in its rule administrations for which a
22 written directive is required, and staff feels that
23 quantities for which a written directive is required
24 is better terminology than therapeutic quantities.
25 Therapeutic quantities actually we feel narrows the

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1 focus too much at least by implication using therapy
2 because there are other types of use than therapy
3 under 35.390.

4 Next slide, please.

5 We're fine tuning language again. ACMUI
6 recommended using "performing quality control
7 procedures" rather than "calibrate" in various parts
8 of the rule when describing the T&E, the training
9 and experience, that an authorized user should have.
10 ACMUI specified changing "calibrate" to "performing
11 quality control procedures" in some sections and
12 paragraphs, but not in others.

13 Staff agrees that this more general term
14 is appropriate because it's more encompassing and we
15 feel that ACMUI made a good recommendation, but for
16 parallelism it should also be incorporated into uses
17 under 35.392 and 394.

18 Next slide, please.

19 Continuing with fine tuning of the
20 language, in 35.490, ACMUI's language was talking
21 about training experience in inventorying sources,
22 and the word "running" was dropped, and staff feels
23 that "running" should be retained as more
24 meaningful.

25 Here we're talking about brachytherapy

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1 sources and an annual inventory. It's probably not
2 enough, and typically inventories are done on a
3 periodic basis. We feel that a running inventory
4 implies a continuous running inventory of sources
5 and accountability of sources so that running should
6 be retained in the rule.

7 Next slide, please.

8 That sort of covers the major and the
9 minor or wording issues in rule text. Now we're
10 going into the more general area of implementation,
11 and by implementation we mean in this particular
12 context we write into the rule criteria that boards
13 must meet to be recognized by the Nuclear Regulatory
14 Commission or an agreement state, but how does that
15 happen? How does he get listed on the Web site?
16 How does the staff look at the criteria?

17 If there's a reason to de-list the
18 board, how does that happen?

19 Okay. So we have an outline of
20 implementation process that we in the working group
21 have developed, and, again, if you have comments on
22 this and we have time set aside in the discussion, I
23 would appreciate your feedback.

24 The thinking we have is the board would
25 submit an application of some sort, maybe a form of

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1 the check-off list, to the NRC. Staff evaluates
2 that, compares it to requirements in the rule, and
3 if needed, consult with the Advisory Committee on
4 Medical Use of Isotopes during a process of listing
5 a board.

6 The working group feels there's also a
7 need of some sort to maintain this list, and at the
8 very least, boards should notify the NRC or the
9 agreement state that recognized them if they have
10 changes in their requirements for certification.

11 I'm going to reflect back just for a
12 moment on the direction of the SRM, and that was
13 that the NRC would not be expected to inspect
14 boards.

15 The de-listing process, removal of a
16 board, how do we accomplish that? The SRM said to
17 staff, "Monitor medical events. If problems
18 develop, look for root causes if one of them is
19 related to" -- they didn't say root causes. I'm
20 interpreting that, but you know, look for the
21 reasons.

22 And if it's tied to the certification
23 process or some inadequacy therein -- Bill, thank
24 you. Next slide. I'm talking ahead of the slides
25 here. We're on de-listing now.

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1 Look at medical events. Okay?

2 Also, changes in board requirements. If
3 a board changes its processes or its requirements,
4 such as they no longer meet the criteria in the
5 rule, their certifications logically should no
6 longer be recognized.

7 We want to add one point here just to
8 flag it, and David will probably move his head up in
9 anticipation on this. That is that the current rule
10 says boards recognized by the NRC or in an agreement
11 state, and the staff doesn't intend to change that.
12 And so when we're looking at the rule and so on, we
13 need to realize that agreement states will also be
14 involved in the process.

15 In the process, one of the things that
16 we're looking at is listing on the NRC's Web site a
17 little bit more information than just a board is
18 recognized. For example, what agreement state
19 recognized the board; the length of time for which a
20 board certification is valid.

21 As a certified health physicist, my
22 certification is good for four years. The training
23 and experience requirements in Part 35 include a
24 recency of training, which is seven years, and so
25 when someone is evaluating the training and

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1 experience of a person, looking at the board
2 certification, certification should be current, and
3 having that information available would hopefully be
4 helpful to people.

5 Continuing on with the process for de-
6 listing -- next slide, please -- the de-listing
7 process, obviously we'd have NRC staff identifying a
8 potential problem. Interact with the boards to give
9 them an opportunity to respond to findings by staff
10 of some inadequacy on the board's certification
11 process. NRC staff would then evaluate the
12 response.

13 Consult with ACMUI about the problems
14 identified by the staff, and if a decision is made
15 to de-list a board, to notify the Commission of this
16 finding and notify the board of the NRC's
17 determination.

18 Next slide, please.

19 I've covered the major points that I
20 wanted to get at with regard to rule text, as well
21 as with regard to implementation, but let's look at
22 where we go next.

23 We are now writing the proposed rule,
24 and we're getting your early input at this point to
25 make this as good as possible. After we finish the

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1 proposed rule, this will be distributed to agreement
2 states for a 30-day comment period, which we
3 anticipate being in June.

4 These comments will come back. We'll
5 review and prepare the final proposed rule. It will
6 go forward to the Commission in late July. The
7 Commission makes a decision. They send down
8 probably another SRM with maybe some direction to
9 the staff like we received for preparing the
10 proposed rule.

11 Then we will make any changes the
12 Commission requires and publish the proposed rule in
13 the Federal Register. And it will be there for a
14 75-day comment period. You all get a chance to
15 comment again, as well as everybody else in the
16 public.

17 After the end of the comment period, the
18 staff will analyze the comments, reconcile them, put
19 them into -- make adjustments as appropriate in the
20 final rule, and we'll go forward with publishing a
21 final rule, and our goal is to have that final rule
22 in place before Subpart J expires in October of
23 2004.

24 In terms of getting input at this stage
25 now, the staff needs to get input quickly. If you

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1 decide you want to make an additional comments after
2 this meeting -- and I'm addressing this especially
3 to members of the boards that are represented
4 here -- please get this back to us by May 30th
5 because we've got a really tight time schedule. You
6 can appreciate that, but it's important that we get
7 this rule out so that it's in place to solve the
8 problem.

9 Okay. That concludes my slides. I want
10 to thank the person back in the booth for taking
11 care of the slides, and we can turn those off.

12 Thank you.

13 MS. WASTLER: I would point out, first
14 of all, that with regards to the comments and the
15 time frame, you know, should you have additional
16 comments, we would encourage you to send them by E-
17 mail to us. At this particular stage, it is, I
18 think, more efficient, and we don't need to be quite
19 as formal as in the proposed rule.

20 So we can get you --

21 MR. BROSEUS: If you have a comment,
22 send it to me, rwbnrc.gov.

23 MS. WASTLER: That's rwbnrc.gov.

24 MR. BROSEUS: Roger W. Broseus.

25 MS. WASTLER: All right. With that

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1 we're actually a little ahead of schedule. So we're
2 going to open it up. I think Roger has got the
3 discussions broken up into two parts, talking this
4 morning until about 10:30 before break on the SRM,
5 criteria for recognition, especially the didactic
6 training and experience, and talk about
7 implementation later, but we'll kind of go through
8 and see how things develop.

9 With that, Mr. Mauer.

10 MR. MAUER: I had a question. Roger, in
11 your review towards the end there when you were
12 talking about the de-listing process, you mentioned
13 about what's often referred to in medicine as
14 maintenance of competency or the recentness of
15 training.

16 Were you indicating that you would
17 expect the boards to reevaluate the board certified
18 candidates in terms of maintaining some form of
19 recertification process?

20 MR. BROSEUS: No.

21 MR. MAUER: Or you actually will have
22 the boards recertify on a regular --

23 MR. BROSEUS: This is a responsibility
24 that rests with licensees basically to make sure
25 that their radiation safety officer, authorized

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1 users, whoever have training that is recent. That's
2 a more pervasive thing. That's not a burden on
3 boards, as I read it.

4 MS. HOLAHAN: And you asked about the
5 recentness of the board certification. I don't
6 think we're going to ask the boards to recertify
7 unless something is changed.

8 MR. BROSEUS: I'd like to keep any
9 implementation issues for later in the discussion if
10 we can. The first topic we have for participant
11 discussion is Option 3, list boards on our Web site.
12 I don't see a need for a lot of discussion on this
13 because it's sort of dictated in SRM, and I think
14 the staff feels pretty strongly that that's an
15 appropriate one.

16 A lot of people, I feel, in the public
17 also think it's a good idea to list them on the Web
18 site, but are there any comments or questions or
19 issues with regard to listing boards on the Web site
20 rather than rule text?

21 MS. WASTLER: Dr. Hendee?

22 MR. HENDEE: The response of the
23 American Board of Radiology to that specific issue
24 is we're fine with that. If the NRC believes that
25 that's the best way to let people know that you

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1 recognize these boards as default pathways, we're
2 very comfortable with that. We would support that,
3 putting them on the Web site rather than building
4 them into the rule itself.

5 That's not why I had my card up.

6 MR. BROSEUS: Why do you have your card
7 up?

8 MS. WASTLER: That would be fine.

9 MR. HENDEE: I want to discuss -- I want
10 to give some clarity on exactly what does it take
11 for a board to be considered a default pathway to
12 recognition of any of the categories, radiation
13 safety officer, authorized user, authorized medical
14 physicist, authorized nuclear pharmacist because I
15 can't tell from reading this rule.

16 MR. BROSEUS: Okay.

17 MR. HENDEE: Are you saying that for a
18 board to be recognized by the NRC as default pathway
19 the individuals who are certified by that board must
20 receive and you must have some documentation that
21 they received all of the training, that they meet
22 all of the requirements that you list in the
23 alternate pathway for boards to be recognized?

24 I'm talking about the ones that are
25 listed here. In other words, for the American Board

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1 of Radiology, let's just take radiation safety
2 officer. For the American Board of Radiology in its
3 certification process, to be recognized as a default
4 pathway to radiation safety, does that mean that we
5 have to show that the board has to require
6 candidates coming into the board process to meet all
7 of the requirements that you have listed down here
8 as an alternate specialty board recognition: five
9 years of experience in health physics, a Bachelor's
10 degree or a graduate degree, a written statement?

11 And does it also mean the they have to
12 have an educational program that consists of 200
13 hours of didactic training?

14 So I'm trying to understand --

15 MR. BROSEUS: To make it a short and
16 sweet answer I think that gets at is that part
17 wouldn't change actually. It's a continuation of a
18 board -- this is staff thinking now, okay? -- that
19 would still exist, that is, that a board would meet
20 the existing criteria on the alternate pathway, all
21 of those that are listed.

22 We're not changing that, except with
23 some minor wording changes that ACMUI has
24 introduced. So there would be two things that a
25 board could do to have its certification recognized.

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1 One would be to meet the criteria that
2 ACMUI has developed, and I'll loosely term that
3 substituting academics and other training and
4 experience for the long list in the alternate
5 pathway, or the board could do what's in the rule
6 now.

7 So the staff thinking is to preserve
8 what's there now, but allow a board also to do the
9 other pathway, which ACMUI has developed. Now,
10 we're not really changing anything in that
11 particular "or" pathway. Is that getting at your --

12 MR. HENDEE: Well, we're getting there.

13 MR. BROSEUS: Or are you asking how the
14 NRC would evaluate today the training and
15 experiential requirements for an RSO in that
16 alternate pathway?

17 MR. HENDEE: It's any of -- I mean, I
18 just chose the RSO. We could talk about any of the
19 other categories.

20 I guess my fundamental question is this.
21 If, in fact, for a board to be recognized as a
22 default pathway by the NRC, that board has to
23 demonstrate that it meets all of the requirements
24 that are otherwise listed here for candidates to be
25 recognized in these categories. Then what's the

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1 point of having the default pathway as a mechanism?

2 It's perfunctory. It becomes relatively
3 meaningless because --

4 MR. BROSEUS: Well, the advantage is
5 that an individual, who may want to be board
6 certified anyway, can get his or her certification
7 by that pathway. They don't have to submit an
8 application to the NRC to review training and
9 experience, et cetera, and then the board
10 certification serves to establish the credentials of
11 that individual.

12 Trish, did you have something you wanted
13 to add?

14 MR. HENDEE: Yeah, I'm not done with
15 this issue, but go ahead.

16 MS. HOLAHAN: Yeah, I think I understand
17 your question, and it's asking is there anything
18 different in the alternate pathway versus the board
19 pathway, and that was one of the things that ACMUI
20 recognized last year at their meeting.

21 They said they didn't want to
22 marginalize the boards, and the thinking is that
23 they put in the boards to be recognized assuming
24 that you could meet the intent of the alternate
25 pathway, but you don't have to have specific hours.

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1 But you have to cover all of the things that are
2 listed in the alternate pathway.

3 MR. HENDEE: So to apply to be
4 recognized as a default pathway, what does the
5 American Board of Radiology or any of the other
6 boards have to submit to the NRC to get that
7 recognition?

8 MR. BROSEUS: Today?

9 MR. HENDEE: Well, I mean whenever the
10 rule becomes effective. You'll have boards applying
11 to be recognized in the default pathway.

12 MR. BROSEUS: Oh, that's what we want to
13 talk about in the implementation discussion. Right
14 now I'd like to concentrate on --

15 MR. HENDEE: Okay.

16 MR. BROSEUS: -- what are the criteria
17 and so on.

18 MR. HENDEE: Okay.

19 MR. BROSEUS: Well, actually I think
20 there are two questions going on simultaneously.
21 Part of it is the process. How do you get
22 recognized? And the other one was how does it get
23 measured.

24 I really think how does it get measured
25 is later. We set forth criteria, and you know,

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1 we're working with ACMUI's recommendations, and if
2 we look at ACMUI's recommendations in the Attachment
3 2, it's certified by a specialty board. It requires
4 all diplomates to hold a Bachelor's degree, to have
5 five or more years of professional experience.
6 There's about four criteria there.

7 And this is substituting for all of the
8 other things that are in the rule now. And ACMUI
9 and I think board representatives in the past felt
10 that that was a desirable alternative, and so the
11 staff's task to them would be to say, you know,
12 "Collect the information from the boards and measure
13 it against that particular set of criteria that
14 ACMUI has developed.

15 MR. HENDÉE: Okay. Now, if a board does
16 not satisfy these requirements exactly, then it
17 would be the expectation of the NRC that to be
18 recognized as a default pathway, the board would
19 have to change its admission criteria to board
20 certification if it wanted its board certification
21 process recognized as the default pathway.

22 In other words, the NRC would require
23 the board to change after years and years of
24 experience of the board establishing criteria for
25 what it considers to be assurance that its

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1 diplomates in practice safely and effectively, but
2 in spite of that ACMUI and the NRC would want the
3 board to change its admissions criteria in order to
4 be recognized as a default pathway for
5 acknowledgement as a radiation safety officer
6 authorized user, authorized nuclear pharmacy.

7 Is that what you're saying?

8 MR. BROSEUS: I don't think that if a
9 board's certification process didn't meet the rule -
10 - they'd almost have to. Otherwise how could they
11 be recognized by the NRC or an agreement state.

12 However, the word I've got is that the
13 expectation is that most boards will be able to meet
14 what ACMUI has written in their draft and their
15 recommendations, and so I don't see it as a real
16 issue from what I understand.

17 MS. HOLAHAN: Looking at the B pathway,
18 you have to hold a Bachelor's or graduate degree
19 from an accredited college. I'm looking at 35.50.

20 MR. HENDEE: Yeah, me, too.

21 MS. HOLAHAN: Have five or more years of
22 professional experience in health physics; provide a
23 written statement, preceptor statement.

24 MR. HENDEE: Okay. Can we just stop
25 with that one because that's a good example? That's

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1 a good example.

2 The American Board of Radiology has
3 certified physicists since 1947. Many of those
4 physicists serve as radiation safety officers, a lot
5 of them. There are probably more physicists
6 certified by the Board of Radiology to serve as
7 radiation safety officers in the clinical
8 environment than are certified by all of the other
9 boards put together in the clinical environment.

10 The Board of Radiology does not meet
11 this requirement. It does not require five years of
12 experience prior to board certification. Therefore,
13 in spite of 47, 53, 56 years of experience, we would
14 have to change our admission criteria in order to
15 meet the five years of experience.

16 Our requirement is a graduate degree and
17 three years of experience, and we give credit for
18 the graduate degree up to one year, but that doesn't
19 constitute five years of experience as you've
20 defined it.

21 So that's a good example of where we're
22 in discordance.

23 MS. HOLAHAN: Okay.

24 MR. HENDEE: And I'm hearing you say
25 that we would have to change and actually require

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1 additional experience prior to board certification
2 for our diplomates to be acknowledged as radiation
3 safety officers according to your criteria; is that
4 correct?

5 MS. HOLAHAN: Well, you say you have
6 three years, and the rule actually allows for
7 graduate training to be submitted for two years, and
8 you indicated that there's only one year given.
9 Unless you can change your requirement for graduate
10 training to be giving two years of credit, you
11 probably have to change your --

12 MR. HENDEE: You don't think that's
13 overly prescriptive?

14 There are other examples. This is just
15 an example. Please understand I'm not just picking
16 on this one point.

17 MS. HOLAHAN: Yeah.

18 MR. HENDEE: You don't think you're
19 being overly prescriptive here in setting up the --
20 in ACMUI and NRC setting up themselves as the -- in
21 a position where you're forcing the boards to
22 actually change their eligibility requirement in
23 order to meet your requirement? Don't you think
24 that's a bit overly prescriptive?

25 MS. HOLAHAN: Well, I understood that

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1 the ACMUI met with all of the boards. The
2 subcommittee met with all of the boards last summer.

3 MR. HENDEE: We did. We discussed this
4 issue then.

5 MS. HOLAHAN: Oh, did you? Okay. So I
6 can't answer that.

7 MR. HENDEE: Perhaps we can discuss that
8 this afternoon.

9 MS. HOLAHAN: Yeah.

10 MR. BROSEUS: You're going to bring this
11 up with ACMUI, right?

12 MR. HENDEE: I am.

13 MS. HOLAHAN: Okay. That's good.

14 MR. BROSEUS: Yeah. So --

15 MR. HENDEE: I'll take my card down. I
16 have a lot of other issues, but we'll stay on this
17 issue for a while.

18 MR. BROSEUS: Yeah. So I think let's
19 keep it with ACMUI also.

20 MR. HENDEE: Yes.

21 MR. VANEK: Ken Vanek.

22 I'm going to pick up a little bit with
23 what Dr. Hendee was saying here because I guess
24 perhaps because of some comments and so on that were
25 made on the original rulemaking thing that the

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1 number of hours specifically versus just topics --
2 now, Trish, you mentioned that number of hours
3 wouldn't necessarily be descriptive within the
4 board, but I'm reading another message through some
5 of this documentation that they feel that the board
6 should at least meet these number of hours of
7 instruction.

8 So is that the intent here?

9 MR. BROSEUS: Are you talking about what
10 I have loosely termed the alternate pathway?

11 MR. VANEK: That's correct.

12 MR. BROSEUS: No. A board could be
13 certified, have its certification recognized using
14 other criteria, and those are the criteria where
15 here -- and he was addressing those; Dr. Hendee was
16 -- and that would be for health physicist, hold a
17 Bachelor's degree, et cetera, et cetera, and there
18 are the other areas, medical physics, nuclear
19 pharmacist, and so on. Have alternate criteria set
20 up also.

21 It doesn't have those 700 hours of
22 training and so on as a way of a board being
23 recognized.

24 MR. VANEK: Okay. Because, I mean, I go
25 back historically as well as to what we've

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1 historically been doing because the board process
2 itself being the fact you have to have a certain
3 amount of training and experience, but then the
4 board process itself of actually going through
5 having a general written examination part, then
6 having your specialty examination part, then having
7 an oral examination part.

8 Whereas alternate pathways, you can sit
9 into a special course and just pay your tuition and
10 get your certificate that said, "I have X number of
11 hours of experience and, therefore, I am now
12 qualified."

13 You know, there's a whole big difference
14 between those two pathways. Just because you sat in
15 a course doesn't mean that you have actually been
16 examined by peers, et cetera, and have been found to
17 have a basic level of knowledge.

18 MR. BROSEUS: Well, I think that
19 particular pathway you're talking about was examined
20 and evaluated during the rulemaking process, and
21 it's there. It's on the books. That's not part of
22 what we're changing now.

23 We're just looking at the board
24 certification.

25 MR. VANEK: Okay. So in order for a

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1 board to then get approval, then again going back to
2 the guidelines that the NRC is going to look at to
3 say, "Okay. Well, this is what we're going to
4 approve," then are we just talking then about what
5 your initial comment was, just the fact that these
6 topics have been covered in a training program, and
7 that they have been examined over these topics?

8 MS. HOLAHAN: Yes, for the board
9 certification pathway because we're assuming that
10 you cover all of the individual things in your five
11 years of experience because that's what's here.

12 MR. VANEK: So we just really need to
13 say that during the examination process that we have
14 actually examining over these areas?

15 MS. HOLAHAN: Yes.

16 MR. VANEK: Okay.

17 MR. BROSEUS: Do you think that's
18 something that should be part of the supplementary
19 information?

20 MR. VANEK: Well, I do. It's just sort
21 of like --

22 MR. BROSEUS: You know, you get into an
23 area where it becomes very prescriptive, and you
24 have people looking, reading your exams, too.
25 There's two sides to that.

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1 MR. VANEK: Well, but we give our
2 examinees, you know, "This is what you're going to
3 be examined over. These are topics you're going to
4 be examined over." So I mean that's not really
5 saying you're telling them what the questions are.

6 You're saying you're going to be
7 examined over these particular areas. So I don't
8 think that that's anything that would be proprietary
9 from that point.

10 Now, and it's a little bit different,
11 too. I mean, if I was going to be an RSO for a
12 broad scope license, I think I would have to have a
13 certain amount of extra training and experience
14 compared to just a little nuclear community hospital
15 with nuclear medicine, but --

16 MR. BROSEUS: But there's another part
17 of this that gets to the issue you're raising, which
18 is, as I understand it, in the alternate pathway,
19 but the potential is there in the board
20 certification pathway. Does the person really have
21 the knowledge and the experience that's needed?

22 And that's an awfully hard thing to
23 measure, but an additional step the Commission has
24 taken is to say, "We require a preceptor statement
25 that says this person has got what it takes."

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1 MS. HOLAHAN: In radiation safety only.
2 The Commission has focused on radiation safety.
3 They're not focused on clinical competency.

4 MR. BROSEUS: Yeah, right.
5 Alan.

6 MR. MAUER: Yes. This question of
7 competency and the preceptor statement is one that
8 has been discussed on and off and people have
9 struggled with. Certainly the boards which have
10 very rigid criteria, usually the places that provide
11 training, undergo examination through a review
12 process, there are formal examinations. The boards
13 go through very expensive evaluation of their own
14 training programs and how they evaluate the
15 candidates and require an examination.

16 On the other hand, the alternate pathway
17 just says you have to have experience and training.
18 There is no examination process. There is no
19 measure of competency.

20 So I think, on the one hand, the boards
21 are holding themselves to sort of a higher standard
22 in many ways, and the alternate pathway basically
23 just says all you have to do is have had some
24 experience and training, but there's really no
25 examination.

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1 We're dancing around this question about
2 an examination process and what's going to be
3 required for the boards. The NRC seems to have not
4 wanted to get into the examination area, but the
5 question of competency keep coming up.

6 How do you demonstrate? I think we
7 really need some guidance and some definition of how
8 both the boards and the alternate pathways will
9 demonstrate competency because the preceptor
10 statement as it now appears on the Web site and is
11 worded says this person is competent.

12 And I think the boards know how to go
13 about examining for competency. We have
14 examinations, and we actually test people. The
15 alternate pathway doesn't have a way to measure
16 competency.

17 So if you're going to establish criteria
18 at the board, I would like a much better definition
19 of how you establish competency, both for the boards
20 and for the alternate pathway, but certainly if we
21 were going to talk about how the boards get
22 approval, we need some definition of what is meant
23 by competency.

24 I mean the boards do it in many more
25 ways than the alternate pathway, but if you're going

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1 to say that the boards are going to be held to the
2 same standard as the alternate pathway, how does the
3 alternate pathway establish competency?

4 MR. BROSEUS: Do you have a suggestion
5 about how that definition would come out?

6 MR. MAUER: I think it's very difficult.
7 Ways people demonstrate competency usually is by
8 taking an examination and showing that they have the
9 knowledge and can demonstrate that, and the boards
10 do do that.

11 But what I'm hearing on one hand is the
12 boards are going to be held to all of the things
13 that are in the alternate pathway. Those are the
14 standards and the training requirements. They go a
15 step beyond, but this problem of competency and how
16 you certify that is a big one.

17 MR. BROSEUS: Well, I think though to me
18 what you're saying sounds circular because you're
19 saying the board is able to do this job, and in
20 fact, I think that's the way the rule is being
21 written, with some degree of trust.

22 And so what can we add that isn't there
23 already? How do you measure competency?

24 MR. MAUER: The board would do it in a
25 traditional way, but when you're looking at

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1 competency in particularly radiation safety, I guess
2 what I'm struggling with is -- and it goes back to
3 the preceptor statement -- the preceptor is going to
4 have to say this person is competent. By what
5 criteria are they going to demonstrate competency?
6 And how are you going to tell the boards to do that?

7 MR. BROSEUS: Dr. Sayed.

8 MR. SAYED: If I may follow up, if I'm
9 understanding Alan correctly here, you're expecting
10 the board to verify competency, which they do by the
11 process of examination, and you're expecting the
12 boards to meet the criteria that you've outlined
13 under the alternate path, but you're not holding
14 people who qualify under the alternate path to the
15 same standard you're expecting the boards to live up
16 to.

17 The candidates who become RSO through
18 the board certification process would meet all of
19 the requirements, plus take the exam and verify
20 their competencies. Whereas those who qualify
21 through the alternate path would take the curriculum
22 as outlined and no exam, no verification of
23 competency. Yet they're qualified as RSOs?

24 MS. HOLAHAN: There is a verification of
25 competency. Somebody has to sign the precept

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1 statement.

2 MR. SAYED: So you have a definition for
3 the or a way to benchmark competency here.

4 MR. HENDEE: I really want to get in on
5 this discussion pretty soon here.

6 MS. HOLAHAN: Okay. Go ahead, Mr.
7 Hendee and then we'll come to Ken.

8 MR. HENDEE: Fine. And I want to come
9 back also to this issue of qualifications that has
10 been raised.

11 But the issue of competency is a very
12 important one. The Board of Radiology has debated
13 whether or not it's possible through any process
14 other than one-on-one supervision of an individual
15 in the practice setting, whether he is a technical
16 person or a clinical person, to really attest to
17 competence. And we have concluded that the board
18 examination does not test competence.

19 I will speak to this at the ACMUI
20 meeting this afternoon. We believe that specialty -
21 - I'm probably going to be in conflict with my
22 colleagues here -- but the Board of Radiology
23 believes that specialty boards evaluate education,
24 training, experience, and mastery of a body of
25 knowledge and its potential applications in a

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1 clinical setting. That's what the board process
2 measures.

3 It does not measure, it does not
4 evaluate the competence or diligence of individuals
5 in conducting technical or medical procedures. We
6 evaluate whether they have the body of knowledge to
7 be competent, but we don't observe the individual on
8 a day-by-day basis practicing his or her specialty
9 and, therefore, we can't really test or evaluate
10 competency in that definition of the word.

11 So I think my recommendation to you is
12 that you should not be addressing the issue of
13 competence either in your rulemaking unless somehow
14 you have a way to test it. You can require a lot of
15 things here, and I think what you do require is
16 exactly what the board process evaluates, but I
17 don't think you require competence because I don't
18 think you have a way to measure it any more than the
19 boards do.

20 MR. BROSEUS: Dr. Vanek.

21 MR. VANEK: Ken Vanek.

22 I'm glad that was clarified because
23 that's one of the things that I was going to ask
24 about true competency versus examining a basic level
25 of knowledge, having the experience and meeting a

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1 baseline.

2 But both the American Association of
3 Medical Physicists, the American College of Medical
4 Physicists, and even the American College of
5 Radiology have all had this talking for quite some
6 time, and we have now all agreed that the definition
7 of a qualified medical physicist is a board
8 certified medical physicist because of the absence
9 of anything else to be able to define a certain
10 baseline of knowledge, training and experience.

11 And many of the states who are now
12 starting to license medical physicists, which is a
13 different issue, but the ones who are do look at
14 board certification as their baseline, and to try to
15 establish, for lack of a better word, competency for
16 meeting that baseline without any examination
17 process, like I said, it only means that somebody
18 attended courses.

19 And that is why I think those three
20 organizations have recognized the board process as
21 the defining thing of being a qualified medical
22 physicist.

23 MR. BROSEUS: Let me come back to the
24 direction that we have from the Commission about the
25 preceptor statement. It says, "Require sufficient

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1 attestation to demonstrate the candidate has
2 knowledge to fulfill the duties of the position for
3 which the certification is sought."

4 And that's what we are going forward
5 with. It's not competency. It's knowledge, and
6 that seems to be what the critical issue that you
7 have.

8 Did I miss something?

9 MR. HENDEE: I agree with you, and I
10 know that you have taken it out of the attestation
11 statement just as you just declared, but there are
12 other places in this document in which you do talk
13 about evaluation of competence, and it includes the
14 board certification default pathway and alternate
15 pathway.

16 So I would just recommend that you go
17 through this document and where the issue of
18 competence comes up you think about changing the
19 wording so that you don't put yourself in the
20 position of measuring something that we all agree
21 really is very difficult to measure.

22 And you substituted wording
23 appropriately in the attestation statement. Now
24 substitute it in other parts of the document
25 similarly.

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1 MR. BROSEUS: And you hit on something
2 that's really important for me as leading the
3 working group. We're doing our very best to get
4 this right and have the right words in.

5 MR. HENDEE: I know.

6 MR. BROSEUS: The problem is I'm human
7 and I'm working with humans, and so if you see
8 something where we didn't hit it, let us know, and
9 that opportunity will be there during the proposed
10 rule process.

11 Okay. Let me see what we had here on
12 the agenda and where we are.

13 MR. HENDEE: I don't want to lose -- can
14 we just come back to one issue? I need
15 clarification now because here's what I hear you
16 saying.

17 I hear you saying that if a board tests
18 candidates in areas that are listed here, then that
19 board could be considered the default pathway
20 without any statement as to the number of hours of
21 experience or training that the candidate would have
22 to have coming into that board exam.

23 As long as the board is testing the
24 candidates for their knowledge of these areas, you
25 would accept that as meeting the conditions for

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1 default pathway. Is that what you're saying?

2 MS. HOLAHAN: That's right.

3 MR. BROSEUS: I really didn't add in
4 hours or anything. It's just what it says here, and
5 the working group hasn't changed that. We've done
6 some fine tuning on words that I talked about
7 earlier today, but the basis is here.

8 Trish, I'm sorry.

9 MS. HOLAHAN: And I believe in some
10 previous discussion we said that in the statement of
11 considerations we can make that clear.

12 MR. HENDEE: Yes.

13 MS. HOLAHAN: The differentiation.

14 MR. HENDEE: Yeah, yeah. That's a great
15 help.

16 MS. HOLAHAN: Dr. Van Decker?

17 MR. VAN DECKER: Yeah, I apologize for
18 being a little late here this morning. The train
19 from Philly doesn't run as quickly as I'd like.

20 MR. BROSEUS: Excuse me for not
21 recognizing you when you came in.

22 MR. VAN DECKER: That's okay.

23 I'm going to need some clarification. I
24 guess I'm hearing some of this conversation. You
25 know, I've actually been somewhat amused that in the

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1 last year and a half some of this has heated up in
2 this discussion when this process has really gone on
3 for seven years now, and the initial five and a half
4 years when I was at the table there was much less of
5 this type of a discussion going on.

6 But I guess my question when we're
7 talking about this default pathway and number of
8 hours and boards, the initial thought process that
9 had gone through a lot of consensus building was
10 that there should be some level playing field body
11 of knowledge across a broad body of practitioners
12 that we all believed was core essence to
13 understanding radiation safety and going on with
14 appropriate use of ionizing radiation.

15 And some of the early concerns had been
16 that boards being deemed boards in the rule, what
17 that meant compared to people who were in alternate
18 pathways or other boards. Were they fulfilling the
19 same criteria and was there an equivalent body of
20 knowledge or at least some gross equivalent body of
21 knowledge that was being tested?

22 And that was the attempt that was coming
23 out of all of that. I think that clarification-wise
24 the alternate pathway was something that had been
25 left in there even after this redo because it's my

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1 understanding that on a legal basis you have to be
2 able to allow people an ability to go through
3 radiation safety training, board certified or not.

4 But I guess my last question was if the
5 boards now are able to regenerate as the years go by
6 their own core for what it takes to sit for the
7 board, then there's no longer this same idea of, you
8 know, what is it across all of these different
9 things that a certain core knowledge base that's
10 going on, although they're on different ways to some
11 degree.

12 And I'm just trying to get a hint of
13 whether that was what this last piece of the
14 conversation was heading towards.

15 MR. HENDEE: Could you just reframe? I
16 lost track of the question.

17 MR. VAN DECKER: Okay. The question was
18 I guess I heard comments to the degree of that a
19 board certification as long as it's testing in
20 specific areas that we consider knowledge base, that
21 the board does not have to specify to those people
22 sitting for the boards what they needed as far as
23 training and experience to sit there.

24 Was that the comment that I --

25 MR. HENDEE: Not at all the intent. We

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1 have a very specific set of criteria for
2 eligibility, for board certification. It includes
3 experience, and it includes experience in the range
4 of areas depending upon which board certification
5 process you're sitting for, and it also requires
6 mastery of body of knowledge on which you will be
7 tested.

8 And we give some general guidelines as
9 to that body of knowledge, but we are not overly
10 explicit because we don't want to be prescriptive in
11 what the person studies.

12 We're not proposing that that be changed
13 at all. The discussion was focused on whether or
14 not if, in fact, as part of the certification
15 process there is one or a series of examinations
16 that test the candidates in terms of their knowledge
17 in areas that are considered to be important to the
18 Nuclear Regulatory Commission in terms of those
19 individuals accepting responsibilities as authorized
20 users, as authorized medical physicists or as
21 radiation safety officers or authorized nuclear
22 pharmacists.

23 And if the board is actually testing
24 those people, that in fact is a better way of
25 measuring their mastery of body of knowledge than

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1 simply hours of training, and I've heard the NRC
2 respond by saying, yes, that would be adequate for a
3 board to be acknowledged as a default pathway to NRC
4 recognition.

5 That's what I've heard.

6 MR. VAN DECKER: In other words then,
7 whatever has been written so far as far as hours or
8 training would not be necessary if one were board
9 certified, testing the appropriate field of
10 knowledge.

11 MR. HENDEE: That's what I understand.

12 MR. BROSEUS: If you look at the --
13 we're kind of retracking over some ground, but if
14 you look at ACMUI's recommendations, I would
15 characterize what they did in certain areas as
16 substituting academic plus experience to the long,
17 detailed list that's in what I have called the
18 alternate pathway.

19 Patricia.

20 MS. HOLAHAN: I just wanted to add but
21 assuming that the examination covers all of the
22 things that are here.

23 MR. HENDEE: Yes.

24 MR. VANEK: And so that, I think, gets
25 back to what is in the understanding when we apply

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1 for approval. We just basically have to say the
2 examination process will cover these things.

3 MS. HOLAHAN: Yes.

4 MR. BROSEUS: You think that's an
5 appropriate thing to have in our discussion of
6 supplementary information.

7 MS. WASTLER: Dr. Mauer?

8 MR. MAUER: And I think what I was
9 hearing in the question of competency, I keep
10 looking at the preceptor form. What I understand is
11 that that term will be removed from the preceptor
12 statement and it will just say that the person has
13 completed the required training. There will be no
14 attestation of competency.

15 MR. BROSEUS: Correct.

16 MR. MAUER: Okay.

17 MR. BROSEUS: And that's determined from
18 the Commission.

19 MS. HOLAHAN: Yes.

20 MR. MAUER: Well, no. The confusion was
21 that I think the ACU -- I can never say that.

22 MS. HOLAHAN: ACMUI.

23 MR. MAUER: -- ACMUI had recommended or
24 said that we didn't want to talk about certification
25 of clinical competency, and then the question was if

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1 you look at the preceptor statement, it says "is
2 competent to independently function, you know, and
3 follow good radiation safety."

4 I just want to be clear that the term
5 "competency," that the preceptor statement is not
6 going to require a statement of competency. It will
7 only require a statement that this candidate has
8 completed the training program.

9 MS. HOLAHAN: And has knowledge to
10 fulfill the duties of the position for which
11 certification is sought. That language would be put
12 into the form there.

13 MR. BROSEUS: It's knowledge based.

14 MR. MAUER: Yeah.

15 MR. BROSEUS: There are some people
16 around the table who haven't really brought up any
17 issues. Rich or Dr. Van Decker, Dr. Sayed, Dr.
18 Ramirez, any comments from you all on these issues?
19 I want to make sure everybody has a chance to speak

20 Sandy, did you?

21 MS. WASTLER: I was just going to
22 recognize Dr. Hendee again. He had his card up.

23 MR. HENDEE: Well, I did have my card up
24 because I wanted to raise another issue, and that is
25 as a follow-up to what Alan has brought up having to

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1 do with the training.

2 Most individuals --

3 MR. BROSEUS: Time out.

4 MR. HENDEE: I'm sorry.

5 MR. BROSEUS: The transcriptionist
6 can't --

7 MR. HENDEE: Yeah. The mic is on, but I
8 was this far away from it.

9 I'm Bill Hendee.

10 Many individuals receive their training
11 that would be necessary to be recognized as
12 authorized users or the other authorized categories
13 as part of their education and training program,
14 part of their actual experience in an educational
15 program either as a resident or as a fellow or as a
16 graduate student.

17 Let's just stay with the residents and
18 fellows programs for just a moment. Those programs
19 are by and large all accredited through the
20 accreditation mechanism, and there is a person who
21 is appointed as the program director, program
22 director for this residency program and this medical
23 specialty or for this fellowship program and this
24 medical specialty.

25 And that program director is really

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1 responsible for assuring to the residency review
2 process and to the Accreditation Council for
3 Graduate Medical Education that, in fact, the
4 education and training of these individuals that are
5 in this program are as represented in the
6 description of the program for which that program is
7 accredited.

8 So the program director is really the
9 responsible individual, and in those situations it's
10 our belief at the American Board of Radiology that
11 that person, that program director is by far the
12 most knowledgeable and most suitable person to sign
13 off on an application to become -- sign off on the
14 attestation statement. Better than an authorized
15 user because an authorized user may be an individual
16 who is working in a particular specialty area, but
17 is not responsible necessarily for the education and
18 training of the individual.

19 So we would recommend that for
20 individuals who receive their education and training
21 in an accredited program or in a recognized
22 fellowship or residency program, that it be the
23 program director who signs off the attestation
24 statement, and then for individuals who receive
25 their experience and training outside of an

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1 accredited program, then it would be appropriate for
2 the authorized user to be the individual signing the
3 preceptor statement.

4 Now, we don't think this is a big deal,
5 but we just think for the NRC's -- I think it makes
6 more sense for the NRC to require the program
7 director to sign off for those individuals who were
8 trained while they were residents or fellows.

9 MR. BROSEUS: Anybody around the table
10 have a comment on that? That's a significant issue.
11 It's an authorized user versus a program director
12 doing that attestation.

13 MR. HENDEE: For those circumstances.

14 MR. BROSEUS: Yeah.

15 MS. WASTLER: Dr. Vanek.

16 MR. VANEK: Actually in the residency
17 programs I think that's a very valid point. From
18 purely a radiation safety point of view, perhaps the
19 medical physicist that teaches it, but the program
20 director does have that responsibility more so than
21 somebody who only taught component of that because
22 as the residents go through at least radiation
23 oncology and os on, they'll have maybe a GU guy and
24 a head-neck guy and this and that, all of which can
25 be an authorized user, but don't have the overall

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1 program and responsible for that program.

2 So basically I think it's a very valid
3 point and for residency programs and fellow
4 programs, it would be very pertinent for that to be.

5 MS. WASTLER: Dr. Sayed.

6 MR. SAYED: That's a good point, but I
7 supposed there should be a statement also including
8 the scientists who do not necessarily receive their
9 training in an accredited or a formalized program
10 where there is a program director who could sign off
11 on that.

12 In other words, these people, the
13 diplomates of the ABSNM are not graduates of
14 accredited residency or fellowship programs. So
15 there are no program directors there. The mentors
16 or their supervisors who they would train and work
17 with in the nuclear medicine clinic would sign off.

18 MS. WASTLER: Right. That would be the
19 authorized user.

20 MR. BROSEUS: That would be the
21 authorized user, yeah.

22 MS. WASTLER: Right.

23 MR. SAYED: As long as that
24 clarification or statement is there.

25 MS. WASTLER: Okay. I think we're

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1 consistent.

2 MR. SAYED: Okay.

3 MR. BROSEUS: So it really says
4 authorized user or program director.

5 MS. WASTLER: Because what we're
6 hearing, at least what I'm hearing, either
7 authorized user or a program director of an
8 accredited residency program or fellowship program
9 would be the two that you're proposing.

10 MR. VANEK: I don't think it's really an
11 "or" when it comes to a formal residency program.
12 If you're from a formal residency program or
13 fellowship program that has a program director, it
14 should be the program director. If a program
15 director is not applicable or whatever, you know,
16 then an authorized user who happens to be the mentor
17 could do it.

18 MS. WASTLER: Okay. I understand.

19 MR. VANEK: So it's not just an "or"
20 type of thing.

21 MS. WASTLER: Right.

22 MR. VAN DECKER: And the only down side
23 to that is what's the life expectancy of the program
24 directors in the current year, and I can tell you
25 across the board it's not usually real long.

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1 I mean, I guess I would kind of prefer
2 in a consensus building of saying someone has really
3 been trained, at least a list of who was involved as
4 the authorized user, oversight people at that period
5 of time that they came out; that somebody has really
6 been personally involved in this person so that we
7 don't have people trading in and out and we know who
8 has really been involved in the training process.

9 But you know I can see why there would
10 be, you know, some utility to that.

11 MR. BROSEUS: How can a person go
12 through a residency program without being under the
13 supervision of an authorized user?

14 MR. VANEK: I mean, you can be under the
15 supervision of an authorized user, but the person
16 who is responsible for the overall training and to
17 make sure that they do get all of that training is
18 the program director, and in an accredited program,
19 even though there may be a turnover of program
20 directors, there's always somebody that has to be
21 the program director if you're going to be
22 accredited.

23 MR. BROSEUS: You're not permitted to
24 allow somebody to use material unless they have
25 proper training, and that's an authorized user

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1 responsibility.

2 MR. VANEK: That's correct.

3 MR. BROSEUS: And so it's kind of going
4 in circles for me.

5 Alan?

6 MR. MAUER: I was going to say I think
7 what you're getting the sense is the way most
8 residency programs work is that the program director
9 is responsible for making sure that the body of
10 knowledge that's required is provided to the
11 trainee. So I think it is much more appropriate to
12 the program director to certify that the body of
13 knowledge has it.

14 In terms of the actual -- and in the
15 preceptor form I had questioned this about a year
16 ago. It says the supervisor. There's a supervisor
17 and then there's a preceptor. When residents work
18 in nuclear medicine or in an area where they're
19 using licensed material, that is under the direction
20 of some other supervisor, which may not be the
21 program director.

22 So we really need to separate body of
23 knowledge and educational training, which is the
24 responsibility of the program director in the actual
25 application of licensed material, which is usually

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1 under a different supervisor.

2 But what I'm hearing is that the NRC is
3 only looking at the body of knowledge that this
4 person has completed a training program and received
5 a certain body of knowledge, and that is the program
6 director's responsibility.

7 If you want to get into certifying
8 adequacy of training in terms of handling and other
9 things, that may be a different individual.

10 MS. WASTLER: All right. I'd just like
11 to take a minute. We're a little bit ahead of
12 schedule, and I've been asked if we could take a
13 short break. So if we move our break up a little
14 bit and take a 15-minute break right now, and we'll
15 come back in 15 minutes and start the discussion
16 again.

17 Would that be acceptable?

18 MR. HENDEE: That's fine. When we come
19 back, I have several issues related to specifically
20 radiation safety and authorized medical physicist --

21 MS. WASTLER: All right.

22 MR. HENDEE: -- in the rulemaking. So
23 we don't want to --

24 MS. WASTLER: No, we won't forget.

25 Thank you.

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1 MR. BROSEUS: So we'll plan in
2 reassembling by the clock on the wall at 10:25.

3 MS. WASTLER: That's right, 10:25.

4 MR. BROSEUS: Ten, twenty-five.

5 MS. WASTLER: And, again, there's
6 coffee. You go out this door, right across the
7 hall, the NUREG cafe.

8 (Whereupon, the foregoing matter went
9 off the record at 10:07 a.m. and went
10 back on the record at 10:27 a.m.)

11 MR. BROSEUS: If we could all
12 reassemble, we're going to resume.

13 We are going to go back on the record.
14 We're resuming after adjourning.

15 I'd like to welcome to the table Howard
16 Dickson. Kathy Pryor was unable to make it, and,
17 Howard, would you identify where you're from and
18 your affiliation and so on?

19 MR. DICKSON: Yes. My name is Howard
20 Dickson. I'm the president of the American Academy
21 of --

22 MR. BROSEUS: Wait. Something is not
23 happening.

24 Can you not hear him? Is the red light
25 on?

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1 MR. DICKSON: The red button is showing.

2 MR. BROSEUS: Can you hear him now?

3 MR. DICKSON: Can you hear me? Well,
4 maybe we can share.

5 MR. BROSEUS: You can maybe share with
6 Dr. Hendee because I think that mic is not working
7 properly.

8 Thank you. Thanks, Bill

9 MR. DICKSON: Once again -- oh, that
10 works -- my name is Howard Dickson. I'm the current
11 president of the American Academy of Health Physics.
12 The American Board of Health Physics is the
13 certifying board within the academy. Kathy Pryor
14 was the outgoing chair of that board.

15 The current chair is Ed Bailey. Neither
16 of those individuals were able to make it. So I'm
17 here sort of in their stead. I certainly didn't
18 want you to get the impression that the American
19 Board of Health Physics was not interested in this
20 meeting or did not want to contribute to this
21 meeting.

22 Certainly our certification program is
23 an elderly one, like Dr. Hendee's, and so we're very
24 proud of the tradition and certainly would like to
25 see the Nuclear Regulatory Commission recognize the

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1 certification process in this particular rule.

2 MR. BROSEUS: Well, we appreciate your
3 stepping forward and volunteering to sit in for
4 Kathy.

5 Somebody brought up just a little fine
6 point. We were talking about wording earlier in my
7 presentation, and I think it was Dr. Sayed that
8 indicated that the word "diplomat" is used
9 throughout -- sorry. He said "diplomate" --
10 throughout the options paper, the SECY paper, and
11 the staff caught that, and we are using the word
12 "diplomate."

13 We may have diplomatic diplomates, but
14 we're using "diplomate."

15 (Laughter.)

16 MS. HOLAHAN: I'd like to make a
17 clarification from what I said earlier. The board
18 recognition process doesn't recognize number of
19 hours for the American -- no, for the RSO and for
20 the medical physicist, but they do recognize a
21 number of hours for 290 and above.

22 And I just wanted to clarify that point,
23 that it was --

24 PARTICIPANT: Thank you.

25 MS. HOLAHAN: Okay.

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1 MR. BROSEUS: Sandy, did you have?

2 Okay. Somebody pointed out during the
3 break there has been a lot of discussion of the
4 using of the word "competency" in our preceptor
5 statement, and the impression was left with some
6 people that we're going to remove that word from the
7 rule, and that's not the intent because the
8 Commission said, "Don't change the wording of" --

9 MR. MAUER: I was just reading --

10 MR. BROSEUS: -- "the preceptor."

11 MR. MAUER: -- Chairman Meserve's
12 comments here.

13 MR. BROSEUS: However, we are going to
14 clarify in the Statements of Consideration what that
15 means, and it's to fulfill the duties, and that's
16 present in the SRM that came down from the
17 Commission. That's the direction to the staff.

18 MS. WASTLER: We can change the
19 preceptor statement itself, but the word
20 "competency" will remain because of the commission's
21 directive, but we will clarify.

22 MR. MAUER: Sorry. That raises problems
23 with some of the earlier discussion that we had.
24 During the break I was reading Chairman Meserve's
25 comments here, and he clearly says he wants to keep

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1 some sort of statement of competency, for lack of
2 another word there.

3 It goes back to the discussion we had
4 earlier about whether the program director then is
5 the one who's the most appropriate to sign the
6 preceptor statement or the authorized user.

7 If the concern of the Commission is to
8 say that this person has had adequate training and
9 has demonstrated the ability to function well as a
10 radiation safety person, the program director in
11 terms of the physician's training, does not work
12 with these candidates in terms of handling
13 radioactive materials and in nuclear medicine.

14 So we get back to this dichotomy between
15 who should be doing the preceptor statement. The
16 program director can best certify the adequacy of
17 the training program and the educational material,
18 but many radiology residents when they rotate to
19 nuclear medicine are not under the supervision of
20 the program director, and there's a disconnect
21 there.

22 So I see a problem.

23 MR. HENDREE: Well, I think the problem
24 is the definition of "competency" and how you are
25 going to define it and how you are going to require

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1 it, and unless you have some insight into this issue
2 that's different from the boards', who have wrestled
3 with this issue for a long, long time and have
4 concluded that really all that you can really
5 measure is mastery of a body of knowledge and its
6 applications.

7 My suggestion to you is that you stay
8 with the wording, but you define competence to be
9 exactly that, mastery of a body of knowledge and its
10 applications, and not try to get into something more
11 subtle that is very hard to evaluate.

12 So I think if you define competency in
13 that way, then it addresses the issue, and you could
14 do that.

15 MR. BROSEUS: Well, I think that we've
16 zeroed in, first of all, in following the SRM, which
17 is having attestations say the candidate has the
18 knowledge to fulfill the duties, and the word
19 "competency" is not there. And it might be useful
20 to expand upon it a little bit using some words like
21 you have suggested in our supplementary information.

22 PARTICIPANT: Some of us can't hear you.

23 MR. BROSEUS: Sorry about that.

24 Are there other comments about this?

25 MR. HENDEE: About this?

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1 MR. BROSEUS: Do you have a new issue?

2 I think we've covered the competency
3 thing now, and I'd like to move on. We need to
4 spend some time also on the implementation, but in
5 our schedule we were scheduled to do that around
6 10:50, and I realize there's some overlap, but do we
7 have any other comments about the criteria, that is,
8 the requirements that the board --

9 MS. HOLAHAN: I think Dr. Hendee had
10 indicated before we broke that he had some issues
11 that he wanted to bring up.

12 MR. BROSEUS: Yeah.

13 MS. HOLAHAN: So why don't we start
14 there?

15 MR. HENDEE: Good.

16 MS. HOLAHAN: And then go forward.

17 MR. HENDEE: I had two issues, both of
18 which pertain to who's qualified to be a radiation
19 safety officer. The first issue you may be able to
20 put to rest very quickly, and that is the in ACMUI
21 recommendations there were, I think, three or four
22 boards listed as default pathways to becoming
23 recognized by the NRC as a radiation safety officer.
24 They included certification in medical health
25 physics by the American Board of Medical Physics,

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1 certification in health physics by the American
2 Board of Health Physics, and certification in
3 radiation protection or something like that by the
4 American Board of Science and Nuclear Medicine.

5 Omitted from that list was the
6 certification board that probably has been
7 responsible for more individuals serving as
8 radiation safety officers than the other boards put
9 together, and that is the American Board of
10 Radiology and its certification process in
11 radiological physics and also in medical nuclear
12 physics.

13 MR. BROSEUS: I think I need to make a
14 clarifying comment right at this point. Excuse me
15 for cutting you off, but the direction in the SRM is
16 not to list in rule text the boards that were listed
17 in I'll call Paragraph A in the ACMUI
18 recommendations.

19 MR. HENDEE: I understand that.

20 MR. BROSEUS: And so the boards will
21 need to meet the criteria that we define in this
22 proposed rule and make application individually, and
23 so it's not predetermined that they're going to be
24 named in the rule. They won't be there.

25 MR. HENDEE: That's possible.

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1 MR. BROSEUS: And so it may be that, you
2 know, these various boards could come forward with
3 their information and meet the criteria and be
4 ready.

5 MR. HENDEE: You're saying that there's
6 no default pathway to becoming a default pathway.

7 (Laughter.)

8 MR. HENDEE: That's fine. That's what I
9 thought you might say, which means, you know, it's
10 all up for grabs now, and every board has to now
11 make its case, and that's fine.

12 So now I will go to my next point.

13 MS. HOLAHAN: Okay.

14 MR. HENDEE: But that was an important
15 point to get clarified.

16 My next point has to do with authorized
17 medical physicists because you point out or it was
18 pointed out that one pathway to becoming a radiation
19 safety officer is to be recognized as an authorized
20 medical physicist, and you might be recognized as an
21 authorized medical physicist by being certified, and
22 there are several possibilities there. I understand
23 there's been no default yet.

24 But it's not clear to me if you are an
25 authorized medical physicist, which means that you

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1 are working in radiation oncologic physics, you're
2 in radiation oncology. By the way that those
3 specifications are worded, it's not clear to me what
4 you can be radiation safety officer of because you
5 can be radiation safety officer of similar types of
6 byproduct material and similar applications of those
7 materials, similar to what you are actually
8 responsible for overseeing as an authorized medical
9 physicist.

10 Well, those sources are typically
11 therapeutic sources, usually sealed sources. So the
12 question is this. Can an authorized medical
13 physicist who is probably a radiation therapy
14 physicist, can that person serve as a radiation
15 safety officer for an institution in which there are
16 uses of unsealed radionuclides in diagnostic
17 medicine, which that individual being a therapy
18 physicist really doesn't have day by day
19 responsibility for, and can he also be responsible
20 for research applications of radionuclides which may
21 be in the unsealed form even though those are not
22 similar types of byproduct material and similar
23 applications to what he deals with in radiation
24 therapy?

25 That needs to be clarified.

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1 MR. BROSEUS: My first answer to that is
2 would that person meet the board certification
3 criteria that we're working on in the proposed rule.
4 If so, yes.

5 Secondly, the alternate pathway still
6 exists, and if a person were listed, you know, if a
7 licensee came forward to the NRC or an agreement
8 state and listed their training and experience and
9 it met the criteria in the rule and the alternate
10 pathway, the answer would be yes.

11 I think you might be getting at another
12 sort of issue where that person wouldn't have that
13 T&E, and therefore may not be qualified to be an
14 RSO.

15 MR. HENDEE: Well, I mean, the issue is
16 the way you have it worded, which is if you are
17 recognized by the NRC as an authorized medical
18 physicist, you can then also be recognized as a
19 radiation safety officer for similar -- I'm not
20 quoting it exactly -- but for similar types of
21 byproduct material used in similar applications.

22 And I don't know what "similar" means.
23 We need clarification of "similar."

24 MR. BROSEUS: I think this really gets
25 into interpreting the existing rule and it's kind of

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1 in Q&A space also, question and answer space, but my
2 guess is that if an individual came forward and
3 their only experience were in some narrow area of
4 radiation oncology physics and they didn't have
5 training and experience for a broad medical program
6 to present the extreme case, they probably wouldn't
7 meet the requirements for T&E to be a radiation
8 safety officer.

9 Trish, do you want to go further with
10 that?

11 MS. HOLAHAN: No.

12 MR. BROSEUS: Alan?

13 MR. MAUER: I'd also like to bring up an
14 item which I think requires some clarification. My
15 understanding is that ACMUI has recommended some
16 modifications to the Part 35 training requirements.
17 So that there may be some changes in the training
18 requirements that come out in the final form.

19 MS. HOLAHAN: In the alternate --

20 MR. MAUER: Yeah.

21 MS. HOLAHAN: -- criteria or the
22 alternate pathway?

23 MR. MAUER: Yes.

24 MS. HOLAHAN: Yes, they did.

25 MR. MAUER: Okay. One thing I want to

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1 bring up that's similar, that there's confusion
2 between brachytherapy, sealed sources, unsealed
3 sources in terms of training.

4 Currently the American Board of Nuclear
5 Medicine is only recognized, and I know that that
6 will change, in terms of meeting requirements for
7 unsealed byproduct material for which a written
8 directive is required for therapy.

9 There are some new therapies that have
10 come along, particularly TheraSpheres. They were
11 classified by the FDA as brachytherapy devices, but,
12 in fact, they are administered in the way unsealed
13 source material is for therapy.

14 And candidates or people at least who
15 have trained through the American Board of Nuclear
16 Medicine training program certainly get all of the
17 physics and training requirements to use unsealed
18 source, but because one thing happens to be
19 classified as a brachytherapy device, they would not
20 be qualified to administer them under the
21 brachytherapy requirements.

22 I can go into the details, and I think
23 that needs to be addressed because training for the
24 use of manual brachytherapy sources excludes and
25 potentially under the new listings would exclude the

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1 American Board of Nuclear Medicine.

2 MS. HOLAHAN: So you're saying that it's
3 listed in 490, and --

4 MR. MAUER: It's listed under 490 which
5 has training requirements that currently, I think,
6 are met by the American Board of Nuclear Medicine,
7 except for some specific things about removal of
8 sealed sources because most things are administered
9 as an unsealed source.

10 MS. HOLAHAN: Yes.

11 MR. MAUER: And it's raised problems for
12 those who were certified by the ABNM right now in
13 terms of getting permission to use these unsealed
14 sources.

15 So I would recommend that the term
16 "unsealed" under 35.390 be removed, and it just says
17 training for use of byproduct material and get rid
18 of the word "unsealed" because some things now are
19 considered sealed sources, but are administered as
20 traditionally unsealed sources.

21 Do you follow that?

22 MR. BROSEUS: Well, one thing I recall
23 from back in the days of doing the guidance. It
24 isn't necessarily so that the NRC will consider our
25 source to be a brachytherapy source because it's

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1 classified that way by the FDA.

2 MR. MAUER: But that's currently the way
3 it's being handled

4 MR. BROSEUS: Okay. It is?

5 MR. MAUER: Yeah.

6 MR. BROSEUS: I'm not familiar with
7 that.

8 MS. HOLAHAN: Yeah.

9 MR. MAUER: So there's a lot of --
10 between sealed and unsealed sources and brachy,
11 those definitions get to be a little blurred.

12 MR. VANEK: You know, for your example
13 though I think one thing might be like a GliaSite
14 with the Iotrex. It's a liquid source that is put
15 into a sealed catheter for treatment.

16 MR. BROSEUS: Okay.

17 MR. VANEK: Leoblastomas.

18 MR. BROSEUS: Right.

19 MR. VANEK: And a clinical perspective
20 in that, it's considered sealed because it's within
21 this catheter and it's removed, and the training and
22 experience for delivering therapeutic doses for
23 something that has also received external beam
24 radiation therapy, I think, are whole different
25 issues.

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1 I mean if that's what you're -- one of
2 the things that you're referring to, I don't think
3 that really accomplishes a lot of the stuff
4 specifically for that, but I think there's a whole
5 bunch of other issues with that particular one.

6 So anyway, but basically I have to look
7 at a lot of ramifications of that.

8 MR. MAUER: I'm just saying that if
9 ACMUI is recommending some changes to the T&E
10 requirements, particularly in the language, maybe we
11 shouldn't be limiting the training requirements of
12 35.390 to unsealed byproduct material but just say
13 byproduct material, which would include those that
14 are under 490 now when appropriate.

15 MS. HOLAHAN: We can certainly take that
16 into consideration.

17 MS. WASTLER: Dr. Vanek?

18 MR. VANEK: I'd like to go back to just
19 a comment that Dr. Hendee was talking about and
20 whether or not, for instance, someone who has as
21 boards and therapy physicists could be included as
22 far as an RSO for nuclear medicine or something like
23 that.

24 It brings up an interesting concept
25 because as far as board exams are concerned, you do

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1 have your general board before you go into your
2 specialty board so the basics of radiation safety
3 and so on should all be covered within that general
4 part of the board exam.

5 But when you take RSOs and, for
6 instance, our RSO at our university is a Master's
7 level health physicist who does not have training
8 and experience with HDR or a lot of the other
9 isotopes specifically, but does that then disqualify
10 him from being an RSO?

11 So, you know, having to have that
12 experience, personal experience and training on
13 every single thing within that license could be a
14 very interesting ramification.

15 MS. HOLAHAN: But if you --

16 MR. VANEK: That's why I'm trying to get
17 what you stated there, Bill.

18 MR. HENDEE: It's a question of similar.
19 It's a question of what do you mean by "similar."

20 MS. HOLAHAN: Yeah, if he's an RSO for
21 the whole facility --

22 MR. VANEK: Yeah, I mean, he's RSO for
23 the whole facility.

24 MS. HOLAHAN: -- you'd want him to have
25 experience with all of the modalities that you have

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1 there.

2 MR. BROSEUS: Well, I think also you're
3 talking about the circumstance if the RSO may have
4 the training and experience for all modalities, and
5 a new come comes along, stereotactic, for example,
6 and he doesn't have experience or even knowledge
7 about the hazards associated with that. Is he now
8 disqualified as the RSO for that particular
9 application?

10 MR. VANEK: I mean, new modalities is a
11 whole other issue because they never become new
12 modalities unless there's somebody that starts using
13 it and developing it to begin.

14 MR. BROSEUS: Well, let's not talk about
15 new modalities. Something he doesn't have
16 experience with.

17 MR. VANEK: Correct.

18 MR. BROSEUS: It hasn't been an
19 institution before.

20 MR. VANEK: Correct.

21 MR. BROSEUS: Then what happens is the
22 question.

23 MR. VANEK: Especially when you're
24 talking about an overall RSO for a large institution
25 who then has within that institution his personal

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1 expert so you could have an RSO of sub-specialty
2 areas, et cetera.

3 But when you're talking about he's the
4 primary RSO for the institution.

5 MR. BROSEUS: I think that that problem
6 existed today independent of the rulemaking we're
7 working on.

8 MR. VANEK: Right.

9 MR. BROSEUS: And it's really, well,
10 what would an institution do if this new modality or
11 let's not call it new modality; this new use came in
12 that they had lacking experience for, and when they
13 go forward with a license application, what would
14 they tell the agreement state or the NRC was the
15 basis for licensure of that particular application?

16 And there would be a need to demonstrate
17 some sort of training experience to be able to
18 license that material.

19 MR. VANEK: And it raises the issue
20 about your having enough RSOs to do what you need.
21 Because I got a little concerned with getting this
22 thing so restrictive that now you have an RSO that's
23 covering 35 institutions and on 35 different little,
24 small community hospital licenses that he may go in
25 once a year or twice a year, is that really

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1 providing what an RSO is supposed to do?

2 Do you know what I'm saying?

3 MS. HOLAHAN: Un-huh.

4 MR. VANEK: You know, I get concerned
5 about that because I think that that is negating
6 what you really want an RSO to do.

7 Now, if you had three levels of RSOs,
8 let's say, and you had an RSO-3 and then maybe he
9 had to be looked at by, you know, someone with more
10 experience periodically, like a quarterly basis or
11 something, but to have guys go around covering
12 multiple institutions just because he's the only one
13 that can really meet all of these requirements, I
14 think, is really taking away what you want an RSO to
15 be doing.

16 MS. HOLAHAN: Yeah. Well, of course, we
17 always say they can delegate their duties, but they
18 don't delegate the responsibility, and they have to
19 sign something that they're responsible for the
20 facility.

21 MR. BROSEUS: Do we also have input on
22 this particular issue?

23 MR. HENDEE: Well, I think the
24 authorized user can qualify as a radiation safety
25 officer as well, right?

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1 MS. HOLAHAN: Yes.

2 MR. HENDEE: So I think this is an
3 issue. It's probably a manageable issue, in
4 general. I'm not so concerned about the radiation
5 safety officer not having experience in
6 sophisticated new applications in radiation oncology
7 because I would hope that there would be a
8 therapeutic physicist.

9 I mean, when you send your license in
10 you've got to demonstrate who is responsible for the
11 use and for the safety of this new device, and in
12 most cases it would be -- certainly in almost all
13 cases it would be an oncology physicist present.
14 You might want to comment on that.

15 I think the big problem is the other
16 way, which is you have an institution that has a
17 therapy program with therapy physicists, and the
18 question is can that therapy physicist also serve as
19 a radiation safety officer for nontherapeutic
20 applications.

21 And I've heard the answer, and I'm happy
22 with the answer, which is if you have the
23 demonstrated experience or training, then you can
24 extrapolate to a wider range of responsibilities in
25 radiation safety.

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1 Now, you might want to rebut that. I
2 don't know.

3 MR. VANEK: No. I mean, it gets back
4 down to what the boards are examining in the general
5 part of the board exam, as you know, and I think
6 that has a big key to it because we do have that
7 general portion in the board exams, and then you get
8 into your specialties.

9 MR. BROSEUS: Our agenda calls for
10 talking about implementation before we finish off
11 today.

12 MS. WASTLER: Dr. Mauer, did you have a
13 comment on another issue or was it on
14 implementation? You have got your --

15 MR. MAUER: Oh, no. That's still
16 standing from the -- I'm sorry.

17 MS. WASTLER: Okay. Dr. Sayed.

18 MR. SAYED: I have a follow-up question
19 on what Dr. Hendee stated earlier under 35.50. I
20 understand that the Section A will be removed and
21 will be listed on a Web page. It specifically
22 states --

23 MR. BROSEUS: We will list boards on a
24 Web page that meet the criteria.

25 MR. SAYED: The criteria, okay. But

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1 within those boards it lists specific specialty
2 areas. Under the new evaluation that you will be
3 implementing and the board will propose to you, will
4 the board be able to add to it the other
5 specialties?

6 For example, here under A-3 it only
7 lists radiation protection, but I believe nuclear
8 medicine or medical nuclear physicists are just as
9 qualified and trained to be radiation safety
10 officers as those who sit only for the radiation
11 protection specialty of the ABSNM exam.

12 MR. BROSEUS: That's what we were
13 talking about in my answer to Dr. Hendee earlier.
14 You know, if a medical physicist or an oncology
15 physicist or whatever meets the requirements, then,
16 you know, for RSO, then they --

17 MR. SAYED: So that's my intent, is just
18 to clarify this. When the board submits to you all
19 of the criteria and you will list those specialties
20 as communicated to you by the board that meet these
21 criteria?

22 MS. HOLAHAN: Yes.

23 MR. SAYED: Okay. Thanks.

24 MR. BROSEUS: And they will be aligned
25 with 50, 51, you know, RSO, medical physicist,

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1 nuclear pharmacist, or the areas of use, 190, 290,
2 and so on for an authorized user.

3 Sandy?

4 MS. WASTLER: According to the schedule
5 or to the agenda, at 10:50 we wanted to start
6 discussion or take your comments on the
7 implementation, on the process for board
8 recognition, but before we do that, do we have any
9 last minute clarifications or points on the issues
10 that we've discussed up to this point?

11 MR. BROSEUS: There was one I think Dr.
12 Hendee might address that was the basis for the
13 Canadian board that we talked about. Did you have
14 something to say about that?

15 MR. HENDEE: I think that the way I read
16 this I just saw this this morning. Are you
17 recognizing an accrediting agency rather than a
18 certifying board?

19 I think the Royal College of Canadian
20 Physicians accredits residency programs, does it
21 not?

22 MR. BROSEUS: Yes.

23 MS. HOLAHAN: Yes.

24 MR. HENDEE: It would not be an
25 individual board. That is not a board that

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1 certifies individuals the way the --

2 MR. BROSEUS: Correct.

3 MR. HENDEE: -- that you're talking
4 about recognizing here.

5 MR. BROSEUS: Correct, yeah, yeah. I
6 mean, like this particular board was added to the
7 list, and it is in Subpart J now, for those entities
8 that -- and I'm going to use terminology kind of
9 loosely here -- that accredit residency programs.
10 It's not in the area that we're addressing as the
11 bigger part of our rule, a certification board.
12 It's not for the specialty boards to be recognized
13 to be an authorized user or whatever. Okay?

14 MS. HOLAHAN: Well, it's both because --

15 MR. BROSEUS: Yeah, it is.

16 MS. HOLAHAN: -- they have the Royal
17 College of Physicians and Surgeons of Canada
18 recognizes the board, and then also a certification
19 specialty.

20 MR. BROSEUS: Yeah, for one of the
21 areas. Which area was that?

22 MS. HOLAHAN: Three, ninety.

23 MR. BROSEUS: Three, ninety.

24 MS. HOLAHAN: They list it under A-3.
25 It's specifically listed, and then certifying in B,

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1 they list the Royal College of Physicians and
2 Surgeons of Canada, and we want to know if there's a
3 basis to list the Royal College of Physicians and
4 Surgeons of Canada in the rule text.

5 MR. BROSEUS: We'll raise this with
6 ACMUI this afternoon, too, but if there's anybody
7 that has a view on this here.

8 MR. HENDEE: Thirty-five, three, ninety?

9 MS. HOLAHAN: Yes.

10 MR. HENDEE: I'd have to read that.

11 MS. HOLAHAN: Okay. It's listed
12 elsewhere, but specifically I caught it in 390

13 MR. BROSEUS: Thanks for clarifying it.

14 MS. HOLAHAN: Okay.

15 MR. BROSEUS: I'm sorry.

16 Well, we can come back to that after we
17 talk about implementation. Shall we move right on
18 into the implementation?

19 MS. WASTLER: Yes.

20 MR. BROSEUS: Because this is an
21 important area, and it's the one where things are a
22 little fuzzier, especially for the working group,
23 and so I briefly outlined the approach of the
24 working group this morning about the processes that
25 we're considering, and please step forward with any

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1 comments or recommendations that you have.

2 Alan.

3 MR. MAUER: I guess I'm unclear a little
4 bit when you're talking about implementation. You
5 want suggestions from us as to how things will move
6 forward?

7 MR. BROSEUS: Let me clarify first.

8 MR. MAUER: Subpart J disappears in?

9 MR. BROSEUS: October 2004.

10 MR. MAUER: 2004.

11 MS. HOLAHAN: So the boards are going to
12 have to resubmit to meet the new criteria in the
13 rule.

14 MR. MAUER: Okay, and I had one
15 particular question. I'll just bring it up again
16 because it was one of my goals today, is that the
17 ABNM had submitted a letter and received a letter
18 that it would qualify and would be listed on the Web
19 site.

20 So if that was premature, we need to
21 know that. Will they need to resubmit?

22 And I guess there will be some time
23 line.

24 MS. HOLAHAN: We need to get
25 clarification.

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1 MR. MAUER: Yeah, we need clarification
2 on that because I have to go back to the board and
3 say, "Oh, you're going to have to resubmit this
4 whole thing."

5 MS. HOLAHAN: Are you here this
6 afternoon for the ACMUI?

7 MR. MAUER: I will be only for the first
8 hour or two and then I have to leave.

9 MS. HOLAHAN: Okay.

10 MR. MAUER: Do you think it's
11 appropriate to bring it up at that time? It's not
12 the ACMUI that's going to.

13 MS. HOLAHAN: No, no. It's not the
14 ACMUI. I was just thinking of timing.

15 MS. WASTLER: To see if we couldn't get
16 you the answer.

17 MR. MAUER: Oh, yeah, I'll be here.

18 MS. WASTLER: We may not be able to in
19 that time frame.

20 MR. MAUER: But I need to go back to the
21 board in terms of procedures, and do we need to do
22 something.

23 MR. BROSEUS: Give me a copy of the
24 letter.

25 MR. MAUER: Okay.

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1 MR. BROSEUS: And we'll make sure that
2 you get an answer back.

3 MR. MAUER: But so then in terms of the
4 implementation question, the boards need to know
5 that as of a certain date, they're going to have to
6 have submitted what materials and what
7 documentation?

8 My understanding, and I think this is
9 pretty simple actually, I think the NRC has lain
10 down minimum training and education requirements.
11 Basically my understanding is the board just has to
12 say, "We're going to meet all of the training
13 requirements in the alternate pathway, which is the
14 minimum requirements, and if we do so, we will
15 receive what people call deemed status.

16 MS. HOLAHAN: And the preceptor
17 statement.

18 MR. MAUER: And the preceptor statement.
19 But, again, I would like to see some -- and again,
20 there is a preceptor statement that's on the Web
21 site. That's the one that I downloaded, and I would
22 like -- I think everybody well ahead of time ought
23 to see what the exact wording is. Is it going to
24 say "competence"? Is it going to say "completed the
25 training program"? Does it say "completed the

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1 training program and can function"?

2 We need to know that because you're
3 going to get a lot of feedback from people based
4 upon what that final language looks like.

5 MR. BROSEUS: Well, the competency
6 statement -- I mean the preceptor statement is not
7 to change. That's a direction from the Commission.
8 So to clarify this as we talked about before --

9 MR. MAUER: So what is on the Web site
10 right now is the form that will go into effect?

11 PARTICIPANTS: No.

12 MS. WASTLER: The form we can change.
13 What we can't change is in the preceptor statement.
14 It's to be as written. That was the Commission's
15 statement.

16 But we can clarify what was meant in the
17 Statement of Considerations, and we can change the
18 form so that --

19 MS. HOLAHAN: To clarify.

20 MS. WASTLER: -- to clarify as well what
21 we mean.

22 MR. BROSEUS: Actually you're looking at
23 a Form 313(a). We're talking about the possibility
24 of a new form, Alan, that -- in other words, looking
25 at the process, what would a board do to get

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1 recognized? How would the information be conveyed
2 to the NRC?

3 And one possibility is to invent a new
4 form with check-off boxes or something, you know,
5 that says, you know, "Identify the board contact,"
6 et cetera, and check-off boxes and maybe some
7 supplementary information about how they meet the
8 criteria and the rule. Okay?

9 It's not a 313(a). It would be a new
10 form. This form would probably not change because
11 if you're board certified --

12 MR. MAUER: This is the preceptor form
13 right now.

14 MR. BROSEUS: Yeah, okay. So you're
15 saying there might be some content in the preceptor
16 form that needs to be changed also.

17 MR. MAUER: Yes.

18 MR. BROSEUS: Okay. Good point.

19 MR. MAUER: Yes.

20 MR. BROSEUS: Okay. Thanks.

21 MR. MAUER: Definitely

22 MR. BROSEUS: It took a while to get
23 into my thick skull.

24 MR. HENDREE: So how much interaction
25 will there be? If a board submits an application,

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1 we'd like to do this sooner rather than later,
2 actually, and you compare what's in the application
3 to what you believe is the requirements to be
4 recognized as default pathway, and then you say you
5 will consult with ACMUI if necessary, which is fine.

6 But how much interface is there back
7 with the submitting board? I mean, can we negotiate
8 this? Is there -- you don't just get the
9 application and then it goes through a process and
10 we either get an answer, yes, you are a deemed
11 pathway or, no, you are not.

12 I presume there is some dialogue that
13 goes on; is that right?

14 MS. HOLAHAN: Yes.

15 MR. HENDEE: Especially at the beginning
16 when we are all trying to figure out how to do this.

17 MR. BROSEUS: So staff would logically,
18 if they think something is missing or some
19 insufficiency, go back to the board and identify
20 that and give them a chance to respond.

21 MR. HENDEE: Great. That's wonderful.

22 MR. BROSEUS: Yeah.

23 MR. MAUER: Just to clarify, it's under
24 11(b). The current form says, "The individual named
25 in Item 1 is competent to independently function as

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1 an authorized user," and that's the language that I
2 think really needs to be --

3 MS. WASTLER: And that's what we've said
4 that we can change, we will be changing.

5 MR. DICKSON: This is Howard Dickson.

6 When do you think this new application
7 might be available for us?

8 MR. BROSEUS: Well, after the rule is
9 final.

10 MR. DICKSON: Okay.

11 MS. HOLAHAN: Well, it's after the --

12 MR. DICKSON: Oh, a draft.

13 MS. HOLAHAN: Yeah.

14 MR. DICKSON: I think you want comments
15 probably on that form.

16 MR. BROSEUS: Yes.

17 MS. HOLAHAN: Yes.

18 MR. DICKSON: And so we would need to
19 have a form to comment on.

20 MS. HOLAHAN: We can get it out with the
21 proposed rule.

22 MS. WASTLER: Were there any other
23 comments on the implementation process or the
24 process that or the issues, reasons for de-listing a
25 board that were presented earlier?

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1 MR. MAUER: Well, just some general
2 comments. The trend that I got and in reading some
3 of the Commissioners' comments that you handed out,
4 it really seems like if the boards submit and say,
5 "We're going to meet all of the requirements,"
6 they're going to get approval unless there's
7 something glaring that they've left out, which is
8 kind of hard to imagine because they're just going
9 to send back to you and then hopefully implement
10 through their own processes the training
11 requirements.

12 In terms of de-listing or not
13 certifying, actually the language is that they don't
14 want to examine the boards. They're just going to
15 look at the medical events rate, and I don't know.
16 That seems kind of vague to me.

17 MR. HENDEE: That's an impossible
18 criterion.

19 MR. MAUER: Yeah. To hold a board to
20 what individuals, you know, at different
21 institutions are doing, and medical events, as we
22 all know, can be caused by a myriad of things that
23 may not necessarily reflect even what the authorized
24 user did or did not do.

25 So I think the requirements and how the

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1 boards are going to be judged have to somehow be
2 firmed up a little bit more than that.

3 MS. HOLAHAN: Well, that's what we're
4 coming to for advice.

5 MR. MAUER: Oh, okay. You want us to
6 actually tell you how to --

7 MS. HOLAHAN: Well, if you have
8 thoughts, you can share them.

9 MS. WASTLER: Concepts or thoughts, if
10 you could share them.

11 MS. HOLAHAN: Yeah.

12 MR. HENDEE: Okay. This is Bill Hendee.

13 I couldn't agree more with Alan on this
14 point. This one requirement that somehow you're
15 going to have some kind of an evaluation of
16 effectiveness of the board's certification process
17 and let that be a criterion with which you decide
18 whether or not to de-list a board I think is setting
19 up an impossible objective for all of the reasons
20 that you can imagine.

21 But it would certainly be a reason to
22 disqualify a board from being listed if, in fact,
23 they don't adhere to the standards that they have
24 proposed to you in being recognized as a board. I
25 think that would certainly be one thing you could

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1 ask.

2 I mean, in other words, if they require
3 -- if the board says you have to have three years of
4 experience before you can sit for the qualifying
5 examination or you have to graduate from an
6 accredited residency or fellowship program before
7 you can sit for the examination, and then you find
8 out that they're letting anybody come in whether
9 they are accredited from an accredited program or
10 not or whether they have the requisite experience or
11 not, that would certainly be a reason.

12 I mean I think you have to hold the
13 boards to the standards that they agree to be held
14 to when they submitted their application process,
15 and that includes if they change their requirements
16 in a substantial fashion.

17 Because we're always modifying our
18 requirements a little bit here and there just to
19 keep up with the times because new things come into
20 the field. We have to add those.

21 But if you change the requirements in a
22 substantial manner, then we would be obligated to
23 tell you about that. You would be obligated to
24 review whether or not that causes you any concern.

25 Those are the kinds of things, I think,

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1 that you could hold a board to. You're really
2 holding the board to what it said it would do when
3 it became recognized by the NRC.

4 MR. BROSEUS: I'm a staff member now.
5 How would I evaluate the term "substantial"?

6 MR. HENDEE: I'm sorry?

7 MR. BROSEUS: What does "substantial"
8 mean? What should it mean to the staff member
9 evaluating? How would they do that?

10 MR. HENDEE: I think if it has the
11 potential of having an impact on the qualification
12 of individuals to serve in the capacities for which
13 you are recognizing that board as giving deemed
14 status. So, for example, the fact that we decide in
15 radiation oncology that people who are declared
16 authorized users must have experience in a new area
17 would be something that you might want to know
18 about, and we would do that.

19 On the other hand, if we decide that
20 we're going to make some minor change, it might not
21 be. I understand that it's a subjective term, but
22 it would certainly seem to me that anything that
23 would have an impact on the qualifications of those
24 individuals to serve in the capacity for which
25 you're recognizing the board as giving it deemed

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1 status would be how I would define "substantial."

2 MS. HOLAHAN: And I would also add, if I
3 may, that only in the areas of radiation safety.

4 MR. HENDEE: Right.

5 MS. HOLAHAN: Not in clinical
6 competency.

7 MR. HENDEE: Exactly.

8 MR. MAUER: I was going to comment
9 further. I think you need to go beyond just the
10 submission of what the board says. I'm sort of from
11 Missouri. Show me.

12 As Dr. Hendee mentioned, the boards go
13 through -- there is a quality control through the
14 ACGME where there are site visits of the programs,
15 where inspectors go in and actually collect data to
16 show that the program directors are providing the
17 appropriate educational material and training.

18 And I think if you wanted a way to
19 actually see that the boards were doing what they
20 would say, you would require some annual or some
21 review process to show that the programs have been
22 inspected by the board, that they're meeting the
23 training requirements similar to what the boards,
24 most of them, are imposing upon themselves right now
25 to make sure that the programs are performing

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1 adequately.

2 And that requires some form of on-site
3 inspection.

4 MS. HOLAHAN: And do you think we could
5 do that through ACGME or some other --

6 MR. MAUER: Some similar mechanism,
7 yeah. Every board goes through a review process
8 that their training programs meet their
9 requirements, and those training requirements are
10 documented by a site visit, and it's reported back
11 through the ACGME process.

12 MR. BROSEUS: Does that include
13 examination areas of radiation safety?

14 MR. MAUER: That includes everything.
15 You know, when the site visitors go, they go through
16 and the program directors have to provide
17 documentation, list the hours, the lectures, who
18 gave the lectures, the time, and they're going so
19 far as requiring attendance records.

20 Now, I'm not sure that you want to get
21 into it to that level, but you would want to have
22 some mechanism for making sure that that kind of
23 review process is taking place.

24 MS. HOLAHAN: Having been through one, I
25 understand.

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1 MR. MAUER: Yes, right.

2 MR. VAN DECKER: The only comment I was
3 going to make is I think that there's some utility
4 to that, but I think we need to recognize that a lot
5 of those site visits are more for the clinical side
6 of things beyond just the radiation safety, and so
7 obviously if that's a piece of it, that would help
8 you, but there may be other instances where people
9 are just attesting to radiation safety that are not
10 the clinical portions of the program, and so there
11 may be a variety of ways to do that.

12 But I agree with Dr. Hendee. I think
13 that, you know, outcome stuff would be great, but it
14 would be difficult to do, and I think that the real
15 goal is to be sure that everyone is fulfilling the
16 minimum requirements across the board so that
17 there's one standard of care across everyone who's
18 involved in the field.

19 I think that the sticky part of this
20 actually becomes, you know, always the fear that
21 people are going to start going their own ways, and
22 things will kind of look a little different across
23 the field, and if you de-list somebody, what does
24 that mean to those people who were certified at the
25 time that the board was an acceptable form of doing

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1 what they do? Are they now -- have to have a time
2 part on -- you know.

3 Hopefully this is all abstract because
4 we hope we never come to anything like that, I'm
5 sure, across the table, but you could have a
6 situation where you have people who have an old SIR
7 certificate and now their board is no longer
8 recognized and what do they do from there. There
9 are issues.

10 MR. BROSEUS: Let me address that
11 because that did come up in our working group. Can
12 you hear me okay over there?

13 Yeah, because the possibility exists,
14 and one of the things that we plan in the working
15 group is to include some information in the
16 implementation and list that in our supplementary
17 information to deal with that particular topic.

18 It's also why -- underlies additional
19 information the working group feels should be on the
20 Web site, which is how long is a board certification
21 good for, you know.

22 But we plan to look specifically at the
23 circumstance of an individual. It's certified when
24 a board is in good standing, and they shouldn't be
25 left out in the cold if the process was good at one

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1 time.

2 MR. VAN DECKER: This raises an
3 interesting question of recertification of boards
4 the same way we do.

5 MR. BROSEUS: Well, that's it, you know.

6 MR. HENDEE: I want to exercise a word
7 of caution here. I think the American Board of
8 Radiology is probably not different from most boards
9 in that the board certifies individuals to be sure
10 that they have mastery of a body of knowledge and
11 they have knowledge of the clinical utilizations of
12 that body of knowledge for the welfare of patients.

13 And the board admits into its
14 certification process graduates of accredited
15 training programs, residencies, fellowships, or
16 medical physics training programs.

17 Certification, the boards certify and
18 another agency or other agencies accredit the
19 training programs, educational programs, and that's
20 done through the ACGME, and under the ACGME, that's
21 the Accreditation Council for Graduate Medical
22 Education. That is a multi-organizational sponsored
23 council. It stands independently.

24 And then under that, there are many
25 residency review committees, one for each medical

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1 specialty. The residency review committees review
2 the residencies and the fellowships in order to
3 accredit them.

4 The board does not get involved in
5 judging or reviewing or examining the educational
6 programs. That's done by the residency review
7 committee under the ACGME. That's a separate
8 process.

9 So we take the word of those processes
10 and accepting candidates into the board exam, but we
11 don't independently verify the education and
12 training. That's not our role.

13 If, and I think this would be foolish,
14 but if the NRC decided that it wanted to actually go
15 in and evaluate the education and training, you
16 would then have to work with the ACGME and the
17 residency review committees, not with the boards
18 because we don't do that.

19 The education and training is separate
20 from the board's certification process, and I think
21 you can't hold the boards to the responsibility that
22 they are somehow verifying that what they understand
23 is being done is being done.

24 We depend on the ACGME and the residency
25 review committees to take care of that.

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1 MR. VAN DECKER: Which is an argument
2 for authorized user over program director.

3 MR. BROSEUS: Yeah. Aside from that
4 point, I don't see anything that's in the proposed -
5 -

6 MR. HENDEE: No, there's not.

7 MR. BROSEUS: -- stuff and so on. So I
8 don't --

9 MR. HENDEE: This was responding to the
10 discussion.

11 MR. BROSEUS: Okay. More comments on
12 implementation, de-listing?

13 One of the things that the Commission
14 pointed out was something they called due process,
15 which makes the lawyers' hair stand on end, but we
16 need to make sure that if a board is to be de-
17 listed, that there's a procedure there, and the
18 working group has worked through something that we
19 think is pretty good, offers boards opportunity to
20 come back and so on to consult with ACMUI and bring
21 this information to the Commission, not just
22 summarily take them off the list.

23 MS. HOLAHAN: But what I'm hearing you
24 say, and I hope I'm not speaking for anybody in
25 particular, but you think of review process as

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1 probably the best way rather than review of medical
2 events. Okay.

3 MR. HENDEE: Why set yourself up with an
4 impossible criterion to satisfy.

5 MS. HOLAHAN: Yeah.

6 MR. HENDEE: I did have another
7 question. It's on a different issue slightly. Is
8 that okay?

9 MS. HOLAHAN: Un-huh.

10 MR. HENDEE: I'm still a little
11 confused. It's actually in Part 35 as it currently
12 exists. Maybe you can help me with this. I know
13 you're going to extrapolate it, but it's the 70
14 years of experience, 70 years of education before
15 you can become recognized as an authorized user or
16 as an authorized --

17 MR. BROSEUS: Well, no, seven years is
18 the recentness of training.

19 MR. HENDEE: Yeah, recentness of
20 training. Who does that pertain to and what do you
21 mean by "training" and "recentness of training"?
22 Can you just clarify that?

23 MR. BROSEUS: Suppose somebody got board
24 certified eight years ago, and that's what they used
25 as their basis for wanting to be an RSO. If they

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1 didn't have training and experience that kept them
2 up along the way, they don't qualify.

3 MS. HOLAHAN: Or worked in the field.

4 MR. HENDEE: Of course, you recognize
5 that at least from the Board of Radiology's point of
6 view, and the other boards can comment, our
7 recertification process is on a ten-year cycle.

8 But I think what you're saying is that
9 if you're an authorize user, you are by definition
10 gaining experience and training. So you would meet
11 that seven years' requirement.

12 So how do you not meet it? You stop
13 practicing for several years?

14 MS. HOLAHAN: Yes.

15 MR. HENDEE: And then you come back?

16 MS. HOLAHAN: Un-huh.

17 MR. HENDEE: And then you would need to
18 have within the last seven years some additional
19 education and experience.

20 MS. HOLAHAN: Yes.

21 MR. HENDEE: And what would that -- what
22 would constitute that? Just some CME?

23 MS. HOLAHAN: I haven't checked.

24 MR. BROSEUS: What does a board require?

25 MS. HOLAHAN: No, I'd have to check.

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1 MR. BROSEUS: To maintain certification.
2 That's part of it, too, really.

3 MS. HOLAHAN: Well --

4 MR. MAUER: It would seem to me that you
5 would have to redo the minimum training requirements
6 all over again.

7 MR. BROSEUS: Okay.

8 MR. HENDEE: Yeah, the problem here is I
9 think the answer would be, yeah, we've got a
10 maintenance of certification process underway now,
11 but it's on a ten-year cycle, and yours is on a
12 seven-year cycle. I think the only problem here is
13 the difference in the cycles.

14 I mean if you had it at ten years --

15 MR. VANEK: I don't know. I think if,
16 for instance, you know, years ago I was RSO on a
17 broad scope license. Well, now I've been doing
18 radiation, just strictly radiation oncology for a
19 while.

20 So if I came back and said now I was to
21 be RSO on a broad scope license again, does that
22 meet the seven years or is that -- I mean I've been
23 still active, but it's just that I've not
24 specialized primarily in radiation oncology. Does
25 that mean I'm not --

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1 MR. HENDEE: We're all kind of guessing
2 as to what it means. We're looking to you to help
3 us under --

4 MR. VANEK: Right, right, and I'm trying
5 to throw out another example on that seven years.

6 MR. BROSEUS: That's kind of a Q&A for
7 the existing rule really as how would one evaluate
8 the training and experience. What does it take to
9 be -- and it varies between authorized user,
10 radiation safety officer, et cetera, because the
11 American Board of Health Physics certification is
12 good for four year, physicians for ten years.

13 Is it a real issue?

14 MR. HENDEE: It's only --

15 MR. MAUER: Doesn't the language say
16 "training and experience or equivalent experience"?

17 MS. HOLAHAN: Yes.

18 MR. MAUER: It says "equivalent." So it
19 gives a lot of flexibility, and that's -- well, I
20 think the way it's worded is adequate.

21 MR. BROSEUS: Okay.

22 MS. HOLAHAN: Okay. Sally?

23 MR. BROSEUS: Come to the mic.

24 This is Sally Merchant from NRC's Office
25 of Enforcement.

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1 MS. MERCHANT: Is this turned on?

2 I would only comment that that's
3 unchanged from the previous, and it's very, very
4 seldom that we look at training and experience for
5 an applicant to be an authorized user where
6 recentness of training even comes in as a question.

7 In the past when that has happened, it
8 has to be reviewed on an individual basis, and we've
9 most frequently taken to the ACMUI and said, "Here's
10 Dr. So-and-so. Here's what he has been doing the
11 last seven years. Doesn't quite meet. What do you
12 think?"

13 And they generally come up with, well,
14 if he does, depending on the individual, this, this,
15 and this, then he will meet. So it's something that
16 the staff generally -- it's not within their
17 expertise for each individual physician who -- I
18 don't know if I'm being clear.

19 He obviously doesn't meet. So the
20 licensing reviewer can't just put him on, but they
21 also would not make some sort of decision because
22 it's not within our expertise to say that physician
23 X should then do this, this, and this, and we think
24 he would meet.

25 We do take it to the advisory or have

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1 taken it the advisory committee in the past, and
2 there has never been an issue about it. I mean,
3 this is not new.

4 MR. HENDEE: I'm very happy with that
5 answer. I didn't understand it then. I understand
6 it better now. I'm perfectly happy with the answer.

7 MS. HOLAHAN: Okay. Thank you.

8 MR. BROSEUS: Do you think we're ready
9 to open it up for public --

10 MS. WASTLER: I was going to suggest --

11 MR. BROSEUS: One more.

12 MR. VAN DECKER: I only want to say one
13 last thing here. I just want to make sure that we
14 just touch base on it, and that's agreement state
15 recognition. I guess there's nothing that we've
16 said here that has kind of changed with our beliefs
17 we're rolling into this, that we would have one
18 standard of care across the United States of America
19 at a certain point in time with agreement state
20 acceptance of some of this.

21 MR. BROSEUS: Let me state it a
22 different way. The training and experiential
23 requirements and so on -- and correct me if I say it
24 incorrectly -- are Category B.

25 MS. HOLAHAN: Compatibility B.

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1 MR. BROSEUS: Compatibility B, yeah.

2 And so we're not changing that, what
3 they're held to, the states. Okay?

4 Now, states may implement somewhat
5 differently, okay, but they can't change the basic
6 standard.

7 And I think we mentioned a little bit
8 more about this before you came in, Dr. Van Decker,
9 and that is, you know, now in the rule agreement
10 states may list or recognize boards, and there's no
11 change to that.

12 The working group was also looking at
13 tying de-listing primarily back to the state that
14 listed. That's something that you may want to think
15 about, but you know, if a state recognizes a board,
16 we're thinking about, you know, having the primarily
17 responsibility for maintaining, so to speak, the
18 listing be with the agreement state, and also to
19 list on the Web site the state that recognized the
20 board.

21 Yeah, Howard.

22 MR. DICKSON: Just one other thing. I
23 just don't feel like we've covered the maintenance
24 aspect quite adequately. I'm not sure what you're
25 looking for there.

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1 I understand that you would expect the
2 boards to make an initial application, but it looks
3 like you're expecting some continual dialogue with
4 the board with regard to any change in the
5 requirements for certification.

6 Now, I realize those are slowly evolving
7 kinds of things for the most part. So there
8 wouldn't be a lot of communication, but is there
9 going to be some obligation on the board's part to
10 reveal any changes to the NRC which may happen ten
11 years down the road?

12 MR. BROSEUS: Well, that's one of the
13 things we talked about earlier, and that we would
14 see it as being a responsibility of the boards to
15 notify the Commission if --

16 MS. HOLAHAN: If there are substantive
17 changes.

18 MR. BROSEUS: Yeah, for substantive
19 changes in their process.

20 MR. DICKSON: What would the penalties
21 be if they did not?

22 PARTICIPANT: De-listing.

23 MR. BROSEUS: Well, then I would --

24 MR. DICKSON: Would they be de-listed?

25 MR. BROSEUS: No, no. Then the staff

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1 would have to deal with it on an individual case.

2 MR. DICKSON: Well, I'm thinking that
3 there are certainly minor changes that do occur,
4 like passing point determinations. I'm not sure
5 that you --

6 MS. HOLAHAN: That, yes.

7 MR. DICKSON: -- would be particularly
8 interested in those kinds of changes.

9 MR. VAN DECKER: I suspect if you took
10 your radiation safety questions off your test.

11 MS. HOLAHAN: Yes.

12 MS. WASTLER: That might create a
13 problem.

14 MS. HOLAHAN: Yeah.

15 MR. MAUER: It's rare that the boards
16 would be changing things. Usually it's adding
17 things, if anything, but as long as they continue to
18 meet the minimum training requirements, it wouldn't
19 -- I assume you'd have to inform the NRC.

20 MR. BROSEUS: And require preceptor
21 statements

22 MR. MAUER: And require preceptor, but
23 any -- so it may be that the language that you use
24 in specifying that would make clear that changes in
25 the board training program --

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1 MS. WASTLER: You can add all you want.

2 MR. MAUER: You can add as long as you
3 don't change the core requirements for the T&E that
4 are required by the NRC and the preceptor statement.

5 MS. WASTLER: Well, those are very
6 specific words that I think might be appropriate.
7 No?

8 You're shaking your head.

9 MR. BROSEUS: You talked about what the
10 board's process is in the training area.

11 MR. HENDEE: Did you write them down?

12 MR. BROSEUS: Well, we'll have them in
13 the transcript.

14 I'll bet they're in your testimony for
15 this afternoon. No?

16 Okay. We'll go back and look at, you
17 know, what people said here.

18 MS. WASTLER: Unless there are some
19 additional points the boards at the table would like
20 to discuss, I think it would be a good time to open
21 it up to questions from the audience.

22 I'd just ask that when you come to the
23 mic you please identify yourself for the
24 transcriptionist.

25 MS. FAIROBENT: I'm Lynne Fairobent.

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1 I'm the Director of Federal Programs for the
2 American College of Radiology, and I'll give you my
3 card afterwards.

4 There's a couple of things that I think
5 do need clarifying that perhaps weren't brought out
6 in the discussion earlier.

7 First, just by way of clarification on
8 your recentness of training discussion, there is a
9 response in the Statements of Consideration on page
10 20294 of the April 24th publication of the final
11 rule that addresses this, and in fact, it does say
12 that these would be referred back to ACMUI on a
13 case-by-case basis as necessary.

14 So there is, has been deliberation on
15 that issue.

16 The other thing i would like to get some
17 clarification on is recognizing the fact that the
18 agreement states have an additional three years to
19 promulgate their compatible regulations with NRC, I
20 find it a little hard to imagine that an agreement
21 state would, in fact, be the first one to recognize
22 a board that NRC has not already reviewed and
23 determined whether recognized status should be
24 granted.

25 I think that it would be helpful in the

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1 discussion on the rule, especially on the
2 implementation criteria, to have language included
3 that addresses if a board is recognized by NRC. If
4 this is correct, then there is no need to apply to a
5 specific agreement state to obtain recognized status
6 by that state or vice versa.

7 If for some reason a board applies to
8 let's just say the State of Texas first for
9 recognized status, and Texas grants recognized
10 status, there then is no reason to apply to the
11 other 31 agreement states and/or NRC for recognized
12 status.

13 I think that that would be helpful to
14 have that clarification in there, and along with
15 that there may be some reason to consider the case
16 that if a board applies to NRC for initial deemed
17 status and is denied, what happens if they then
18 apply to an agreement state and are accepted, or is
19 that even an option?

20 For example, so if NC has denied deemed
21 status and rather than the board coming back and
22 working with NRC goes to the State of Texas and
23 Texas finds their process acceptable and grants
24 deemed status, I don't know if we're getting into a
25 potential area. Hopefully that would never happen,

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1 but in looking at all of the previous statements of
2 consideration and responses to comment, I have not
3 seen discussion on those items, and I think that
4 that might be very helpful as you're refining the
5 implementation criteria for review and approval of
6 board status.

7 And the only other thing I would ask is
8 in looking at de-listing criteria is to consider
9 there has to have been some criteria used over the
10 multitude of years when the original Part 35 and
11 Subpart J was in existence, and although the boards
12 were hard wired in, I can't imagine that there
13 hadn't been consideration given to what would happen
14 if a hard wired board no longer should be hard
15 wired.

16 And I would just think that if there is
17 history on that, that that should be reflective in
18 how one goes forward in a de-listing process.

19 MS. WASTLER: Okay. Thank you.

20 MR. BROSEUS: Thanks, Lynne.

21 MS. WASTLER: Thank you very much. We
22 will consider those.

23 MR. UFFELMAN: I'm Bill Uffelman,
24 General Counsel and Director of Public Affairs in
25 the Society of Nuclear Medicine. You have my card.

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1 I guess following on my 29 years'
2 experience of drafting regulations and laws, Part
3 356 is a toughie, and I guess a couple of comments.

4 And Dr. Mauer raised the issue, and you
5 responded. One of the things that I think you ought
6 to give some consideration to in this or make some
7 forward thinking how we're going to deal with it in
8 the future is that the reality between unsealed
9 source and sealed source is more a reality of the
10 route of administration rather than whether, in
11 fact, it was deemed to be a sealed source in the
12 case of a SIRSphere or TheraSphere, and as you said,
13 the unsealed material that, in fact, is administered
14 as if it was a traditional sealed source.

15 Whether that means there needs to be a
16 point three-something or other that says that
17 physicians who are trained in this route of
18 administration, you know, can, in fact, be qualified
19 to use these materials or something, there ought to
20 be a way to, in fact, you know, spell out in the
21 rule that there are people who are, in fact,
22 qualified to do things that don't fit exactly in the
23 .390, .490 breakdown that you have established.

24 There's a space in between, if you will,
25 that both, in fact, can cross into.

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1 Going back to the de-listing, I'm not
2 sure and maybe I missed it somewhere, who initiates
3 the de-listing process. Can, in fact, there be a
4 complaining witness, if you will, that writes you
5 and says, "I've noticed that people who are going
6 through a program" -- and perhaps it's -- you know,
7 one of the issues I have is that -- and let's step
8 away from the board. Let's just talk about an
9 alternate process, the B process, if you will, as it
10 is in most of these.

11 Whether in fact there's a preceptor out
12 there who is signing off on people, you know, we
13 have the training program du jour, if you will, that
14 somebody said, you know, "I can make money doing
15 this," and they're doing it, and they are, in fact,
16 signing off as a preceptor.

17 Who, how do you identify an individual
18 who perhaps is abusing the system that, as former
19 counsel of Medical Malpractice Study Commission of
20 the State of Indiana, you know, it may not be
21 malpractice, but there's something fishy, you know,
22 going on, and you perhaps need to, whether it's in
23 the rule or, God forbid, guidance that you spell
24 out, how, in fact, that process -- you know, that
25 there are a list of people who are deemed to not be

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1 qualified to sign off on certain activities and
2 individuals.

3 MR. BROSEUS: Do you have a suggestion?

4 MR. UFFELMAN: What the process would
5 be?

6 MR. BROSEUS: For identifying these
7 people.

8 MR. UFFELMAN: These people?

9 MR. BROSEUS: Yeah. You said don't put
10 them in the rule and don't put them in guidance.
11 What would you do?

12 MR. UFFELMAN: Well, I'm saying it could
13 be in the rule, but I don't see lots of words in the
14 rule about de-listing, but you, in fact, should
15 have a provision that a method for complaining, for
16 a complaint to, in fact, be filed, and it puts it
17 into due process; that an individual who is acting
18 as a preceptor under, you know -- pick a number --
19 50, 290, 390, that they, in fact, are not qualified,
20 and then you would have to have a hearing process by
21 which you would determine whether, in fact.

22 And that then may mean that they get
23 referred back to their appropriate -- you know, how
24 did they become a preceptor? Did they get it by
25 board? You know, do you go back to their original

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1 board that certified them and have them de-listed?

2 You know, you'd have to think about all
3 of the train that that entails, but there ought to
4 be a process that there are people who can't do
5 this.

6 I think those would probably -- you
7 know, you've discussed and highlighted and cussed
8 and all of this. I think you're doing a good job,
9 and I commend you for that.

10 MR. BROSEUS: Thanks.

11 MS. HOLAHAN: Thank you very much.

12 Those are very good --

13 MR. BROSEUS: Great comments, yeah.

14 MS. HOLAHAN: Great comments. Thank
15 you.

16 MR. BROSEUS: Yeah.

17 MR. HEVEZI: Hi. I'm Jim Hevezi,
18 representing the American Society of Therapeutic
19 Radiology and Oncology, and I'd just like to make a
20 couple of comments.

21 With Dr. Uffelman and Dr. Mauer,
22 radiation oncologists are also part and parcel of
23 the users of some of these unsealed sources. There
24 are a lot coming into the fray now with monoclonal
25 antibodies and the like.

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1 Either specialty if they have the
2 required training can use these to help patients,
3 and they probably come from a different direction,
4 but nonetheless, I think the comments made are
5 appropriate in terms of allowing either/or or both
6 to use these radionuclides.

7 The second comment concerning the
8 radiation safety aspects of new technologies Dr.
9 Vanek and Dr. Hendee addressed, and I'd like to
10 support that. Being a radiation oncology medical
11 physicist, we have a radiation safety officer that
12 oversees all of the compliance that we as
13 practitioners need to adhere to during any
14 particular procedure.

15 For example, high dose brachytherapy.
16 Certainly the radiation safety officer can't do what
17 we do in the planning and administration with the
18 radiation oncologist for patient care, but he or she
19 can insure that we're complying with all of the
20 rules and regulations that in Texas -- we're an
21 agreement state -- that Texas has set out for us.

22 And so even new technologies, and as
23 Roger mentioned, new compliance issues will come to
24 the surface as these new technologies get
25 implemented, and the radiation safety officer will

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1 have to insure that they institution and the
2 practitioners are complying with those issues.

3 That's my comments.

4 MS. WASTLER: Thank you very much.

5 Are there any other comments?

6 (No response.)

7 MR. BROSEUS: If there are no other
8 comments, there's one member of the working group
9 who joined us midway through. Ron Zelac over here
10 is with our Materials Safety and Inspection Branch,
11 and I'd like to recognize his contributions to the
12 working group.

13 They're actually our client. At
14 Rulemaking and Guidance, we write the rules, and we
15 have clients, and they are the ones that execute
16 these things, including the implementation.

17 Sandy, I want to go ahead and wind up.

18 MS. WASTLER: Well, unless there are
19 further comments.

20 MR. BROSEUS: I want to express my
21 gratitude to all of you for the time you've taken to
22 think about these issues, to come here and give your
23 considered opinions, and know that we are going to
24 work to do the best we can to give you a good rule.

25 MS. HOLAHAN: I'd just like to say,

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1 again, my thank you, and if you think about anything
2 on the way home, we'd appreciate your comments by
3 May 30th.

4 MR. HENDEE: Well, can we respond by
5 expressing our appreciation for your openness today?
6 We're all trying to accomplish the same thing here,
7 working together, and I think this has been a good
8 meeting, and I think you have certainly clarified a
9 lot of issues.

10 I think you've made it possible for us
11 to work with you and function with you to get this
12 rulemaking going.

13 So we appreciate very much the open
14 atmosphere in which we've had this discussion.

15 MS. HOLAHAN: Thank you very much.

16 MR. HENDEE: Thank you.

17 MR. BROSEUS: If there are no further
18 questions or comments, we're adjourned.

19 (Whereupon, at 11:36 a.m., the meeting
20 was concluded.)
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